Evidence-Based Decision-Making on Medical Technologies in China, Japan, and Singapore

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ABSTRACT

Objective: To review the use of evidence in the market approval process, reimbursement, and price control mechanisms for medicines and medical devices in China, Japan, and Singapore.

Methodology: Documentary reviews relevant to public health policy and management by government authorities.

Results: Drug regulatory authorities play a vital role in the market authorization process of medical technologies. The approval criteria in the three countries are similar to those of the US Food and Drug Administration and many other countries, whose core measures are efficacy, safety, and quality, along with risk-based analyses in China and Singapore. All established the national drug list (Japan) or lists (China and Singapore) for reimbursement.

Although Japan reimburses any drugs listed, China and Singapore selectively reimburse regarding the types of the list. The cost-effectiveness is utilized for prioritization of new drugs listed in Singapore. Japan controls the price by government, whereas Singapore keeps market liberalism, and China maintains a mixture of both.

Conclusion: All three countries have established their own mechanisms, but cost-effectiveness requirements have not been fully introduced yet, partially applied to the reimbursement processes in Singapore.

Keywords: health reform, medical technology, drug regulation, pricing, reimbursement, cost effectiveness.

Introduction

This article was synthesized from three country papers presented at the 3rd ISPOR Asia Pacific Conference in Seoul, Korea on September 6, 2008. The objective of the papers presentation was to review the use of evidence in the market approval process, reimbursement, and price control mechanisms for medicines and medical devices in China, Japan, and Singapore, which is considered to be at an intermediate stage of employing cost-effectiveness requirements in the government policies.

China

To build a “Harmonious Society” as the central goal for China’s development, the state health reform embarks on a major initiative of “Health China 2020,” aiming at providing a universal medical insurance coverage for all citizens by 2020. Under the current state health reform plan, public finance will allocate additional RMB850 billion funds to health care for the next 3 years.

During the rapid economic transition from 1978 through 2009, the Chinese health system has also undergone substantial reforms in recent years. Two distinguished issues are worth noting. First, the total health-care share of GDP is about 4.7%. Although this is a low percentage relative to international standard, the private portion paid out of pocket (OOP) is more than 50% in recent years [2], among the very top tire of countries with the highest OOP payment.

Second, the health delivery system is still highly dominated by the state-owned providers, accounting for 90% of the hospitals nationwide. They challenge with a major dilemma to balance providing low-priced services with accounting for no more than 10% of total average budget because of the reduced public funds.

With the rapidly inflated medical inputs and upgraded technology, public hospitals are left with little options but with greater incentives to seek cross-subsidy revenues by supplying more profitable services. As a result, pharmaceutical use accounts for nearly 50% of the total health expenditures.

Japan

Universal coverage is a feature of health insurance in Japan, established in 1961. About 5000 units of insurers are categorized: Employees’ Health Insurance (EHI) makes up 60%, whereas National Health Insurance (NHI) for nonemployees makes up 40%. Fee-for-service is the principle of payment with copayment of 30% on-site, according to the fee and reimbursement rules biennially revised by the MHLW. The aging society makes NHI financially weaker year by year, shifting the elderly at a higher risk from EHI to NHI. The National Medical Expenditure is USD300 billions, 8% of Japanese GDP, with an increment of USS10 billion per year. Four challenges to reform have been implemented by the MHLW: 1) long-term care insurance since 2000; 2) diagnosis procedure combination since 2003; 3) The Healthcare Systems Reform Act in July 2006; and 4) proposal of the New Pricing System Reform since 2007.

Singapore

Singapore has a hybrid system of health-care delivery. Private general practitioners (GPs) provide 80% of the primary health-care services, whereas the government polyclinics provide the remaining 20%. For the more costly hospital care, it is the reverse situation, with 80% of the hospital care being provided...
by the public sector and the remaining 20% by the private sector (There are 13 public sector and private sector hospitals, respectively. The private hospitals are, however, much smaller in size compared with the public sector hospitals.) [3]. Patients are free to choose providers within the hybrid health-care delivery system. The aim of the Ministry of Health (MOH) is to ensure that patients receive health care that is appropriate to their needs across the continuum of care based on current evidence and clinical knowledge. To achieve this, evidence is employed in various stages of health-care decision-making.

The NHl Systems

China
Currently, China has four major medical insurance schemes available as follows.

The Urban Employment Basic Medical Insurance (UEBMI). The UEBMI is a mandatory insurance scheme for formal sector employees in urban areas. Started in 1998, UEBMI schemes are organized featuring with social pooling account and medical savings account. Funding for the UEBMI comes from premium contributions by employers for about 6% to 8% and by employees for 2% of the beneficiary base salary, respectively [4]. Currently, the UEBMI covers more than 200 million urban-employed population. On the balance sheet, the UEBMI has accumulated fund surplus significantly more than its expenses. The recurrent surplus indicates that the risk pooling capacity is large enough to support an increase in benefit payments without undermining the scheme sustainability. Given these conditions and the health reform effort, the Ministry of Human Resources and Social Security (MHRSS) is expected to take actions aiming at bringing down the surplus by either raising the rate of benefit payment or enlisting some newer drugs on the program formulary.

The New Rural Cooperative Medical Insurance (NRCMI). In 2003, the State Council began to reestablish the NRCMI for farmers. The NRCMI policy specifications include 1) a government subsidy of an RMB 80 premium contribution conditional on an individual contribution of RMB 20 annually; 2) insurance coverage primarily for inpatient care and major outpatient expenses; 3) voluntary enrollment on a family basis; and 4) risk pooling and administration at the county level under the local bureaus of health.

The NRCMI has grown very rapidly in the last few years, covering nearly 850 million people or more than 90% of the total rural population at present. The NRCMI has made a significant progress in providing benefits to the rural population. National statistics show an increase of 15.9% for total health cost and 45.3% up for insurance expenses per enrollee, suggesting an increasing share of the cost burden paid by the insurance. Although the NRCMI was started to reimburse inpatient services, more and more local NRCMI programs have begun to cover outpatient services. Some pilot NRCMI schemes also cover physical examinations and offer fixed subsidies for labor and delivery services.

The Urban Resident Basic Medical Insurance (URBMI). In July 2007, the State Council initiated the URBMI for urban residents. After the pilot experiments in 79 cities, the URBMI has now covered over 100 million urban residents. Similar to the NRCMI, the current URBMI policy settings include government contribution of an RMB 80 premium per enrollee, voluntary participation, insurance against major illnesses treated at inpatient facilities, and a low level of reimbursement due to limited pooling capacity compared with the UEBMI. Based on an evaluation study by Lin et al. [5], the poor and those with previous use of inpatient services are more likely to enroll in the URBMI. These two disadvantaged groups also seem to gain more in terms of access to care and a reduction of their financial burden. In addition, the disadvantaged groups also tend to be more satisfied with URBMI policies.

The URBMI yields two policy implications. First, the State Council is committed to increasing public financing for population health, with social medical insurance as the main approach of health-care financing. Second, the newly initiated URBMI, together with the UEBMI and the NRCMI, serves as a milestone step toward universal health insurance coverage for China by 2010.

Private Medical Insurance (PMI). PMI covers approximately 6% of urban dwellers and 8% of rural individuals. The revenue of the “PMI” market in China is about 30 billion RMB in 2006 as compared to the annual income of the UEBMI of 180 billion RMB. Although relatively small, PMI has gained a foothold and could expand relatively rapidly consistent with the increase in disposable income, increasing urbanization, and demand for quality service, provided appropriate supportive policies are in place. With PMI as a strong complement/supplement to the UEBMI, the financial burden on the government would be reduced, thereby freeing up public funds to be used in rural areas or for those with lower income levels.

Despite growth, PMI still has a very low penetration rate and only accounts for 2% of total health expenditure compared with 20% globally. From a societal perspective, PMI may better help mobilize additional resources within a financially constrained health-care system.

Japan
Japan has a public insurance system for health care that has been covering the whole population since 1961. Even though insurance bodies consist of employer-based, region-based, and mutual aid association-based organizations, health insurance coverage and pricing decisions are uniformly determined by the government.

According to the national medical expenditure report of 2006, total annual medical expenditure in Japan was 33 trillion yen (approximately US$330 billion).

Singapore
The Singapore health-care financing system is based on individual responsibility, coupled with government subsidies, to keep basic health care affordable. Patients are expected to pay part of the cost of medical services that they use and to pay more when they demand a higher level of service. For example, in public sector hospitals, a C class patient enjoys 80% of subsidies while A class patients pay full fees. The difference is in physical amenities—a C class patient is housed in an eight-bedded cubicule, whereas an A class patient has a single room. The clinical care provided is not dependent on the ward class but on the patient’s clinical needs. Patients choose the ward class where they wish to be admitted [6].

Individuals are encouraged to take responsibility for their own health by saving for medical expenses. Under the Medisave scheme (introduced in 1984), all working persons are required by law to set aside 6.5% to 9% of their income into their personal Medisave account which can be used to pay for hospitalization expenses incurred by them or their immediate family members.
Mechanisms and Evidence Used in Market Authorization

China

The State Food and Drug Administration (SFDA) serves as the government regulatory authority to approve all medical drugs and devices to be marketed in China. New and generic applications of domestically manufactured products must be submitted through the local provincial regulatory agencies for initial assessments. Follow-up reviews on clinical trials and final approvals are directed at the central SFDA [10]. With the exception of certain imported over the counter (OTC) products, applications for imported products are submitted directly to the SFDA. The waiting time for the approval of a new drug application is usually between 1 to 2 years.

The approval criteria of the SFDA are similar to those of the US Food and Drug Administration (FDA) and many other countries, whose core measures are efficacy, safety, and quality evaluations of the outcome of preclinical and clinical studies, along with risk-based analyses [11]. Recently, under the health reform initiatives with increasing calls for cost containment, some discussions are engaged on cost-effectiveness as a possible measure to be considered for priority settings.

A major difference exists between the approvals of the SFDA and the US FDA. When approving a product by granting a marketing license, the SFDA requires the licensee to have a manufacturing license for the product. In other words, a drug marketer must also be a drug manufacturer [11]. In contrast, in the United States, a drug marketer can outsource manufacturing to others. This special approval requirement of the SFDA faces increasing challenges, as more and more traditional manufacturers fail to discover new products, whereas many R&D-oriented innovators lack the manufacturing capability, resulting in a 40% idling rate of China’s drug manufacturing capacity [12].

Amid mounting domestic and international pressure, the SFDA is taking encouraging steps to improve its approval policy and practice to make them more compatible with the international standards. These steps include the adoption of the Drug Master File system, the Pre-Approval Inspection requirement, and the emphasis of Quality by Design and Good Review Practice [10]. There have also been welcome discussions on global simultaneous development to speed up multicenter clinical studies [13].

Japan

All drugs and devices must be approved by the Ministry of Health, Labour and Welfare in Japan. In 2004, the Pharmaceuticals and Medical Devices Agency (PMDA) was established as an independent body to consult the approval process and review the submitted materials as well as pharmacovigilance. The PMDA has three main roles. One is to review new drug applications from the viewpoint of safety, efficacy, and quality. Clinical trial data that demonstrate efficacy and safety are required for application. The PMDA also gives advice to each company regarding clinical trial designs. Sometimes clinical trial data in other countries are accepted with bridging studies that include pharmacokinetic/pharmacodynamics studies among Japanese people.

Singapore

The Health Sciences Authority (HSA), a statutory board under the MOH, safeguards public health by ensuring that health products (e.g., drugs, medical devices) in Singapore meet appropriate standards of safety, efficacy, and quality. It employs a risk-stratification strategy in the regulation of health products with different regulatory requirements for the range of health products available here. The requirements for medical devices, for example, are more detailed and stringent than those for cosmetics because they are generally viewed to be of higher risk.

There is also an array of options available for the registration of pharmaceutical and biological health products in Singapore that provides flexibility to companies in planning their regulatory submissions. For instance, if a product has already been approved by at least one competent drug regulatory agency the company can choose an abridged route for registration by submitting data that have been reviewed by that regulatory agency. The review takes about 180 working days (excluding stop clock). There is also a verification route for products already evaluated and approved by at least two of the HSA’s reference drug regulatory agencies—the US FDA, Health Canada, Australian Therapeutics Goods Administration, European Medicines Agency, and the UK Medicines and Health Products Regulatory Agency (“Guidance on Medicinal Product Registration in Singapore” accessed at http://www.hsa.gov.sg). This offers the quickest turnaround of about 60 working days (excluding stop clock). Those products that have not been approved elsewhere have to go through full evaluation by the HSA, which can take about 270 working days (excluding stop clock).

Thorough product assessment does not mean the product is risk-free because the full safety and efficacy profile will only be known when the drug is used in thousands of patients in the “real-world” situation. The HSA has thus supplemented the approval system with a pharmacovigilance system that is able to detect problems early and enhance the knowledge base related to the product.

With the emergence of more complex issues, relying on local knowledge would not be adequate. The HSA has increasingly collaborated internationally and tapped on external panels of experts for advice. This also enables potentially more work sharing between international bodies so as not to duplicate resources.

Once a health product is allowed entry into the Singapore market, health-care professionals are free to prescribe them as required by their patients regardless of whether they are in the public or private sector.

Mechanisms, Processes, and Evidences Used in Decisions for Reimbursement

China

Drugs on the national drug list are reimbursable under the three insurance schemes above. The government introduced the currently existing reimbursement system in the 1990s, pledging to update the national drug reimbursement list (NDRL) every 2 years. Presently the NDRL, managed by the MHRSS, covers about 1027 Western drugs and 823 traditional Chinese medicines (TCMs). The NDRL is separated into two parts: A list (315 Western drugs) and B list (712 Western drugs) and the rest of TCMs. The A list means “Clinic necessary & effective, wide

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coverage, and lower price.” Most of them are local generics with 100% reimbursement; the B list means “Clinic selective & effective; premium priced” including brand products and some imported and/or JVs’ with 10% to 30% patient copayment. Currently, about 700 compound or 15% of drugs are classified as category B and is determined by provincial governments.

The first NDRL was issued in 2000 and revised in 2004 when 40% more pharmaceuticals and 90% more TCMs were added among selected drugs launched before 2003. Currently, there are a large number of new compounds approved by the SFDA and are on the market in China but are excluded from reimbursement as they wait for the next revision. This may impede patient access to new medicines and disincentivizes new development and investment in new pharmaceuticals in China. For example, drug launched since 1997 took an average of 3 years to get on national drug reimbursement listing compared with an average of 6 months for the United States and France and 3 months for Japan.

China appears to have the longest time lag between product launch and gaining reimbursement.

The current health reform has proposed to improve criteria for NDRL inclusion, and in principles they would include frequent clinical need, regional economic conditions, drug usage patterns, efficacy, efficiency, cost-effectiveness, and availability. Nevertheless, it is a great challenge to implement the criteria scientifically in the selection process, which has been much dependent upon expert opinions. In addition, greater effort has been made in the recent reform to reinforce the state essential drug policy, leading to a national essential drug list (EDL). EDL is intended for the selection of a subset of NDRL drugs, but the former would be subject to a much higher standard in terms of safety, effectiveness, cost, and availability measures. Following the state reform policy, EDL drugs must be fully stocked, used, and reimbursed as the first line for popular diseases at all community-based primary health facilities and pharmacies. Based on the most recent policy update, EDL will include around 300 drugs, with about 200 Western medicines and 100 Chinese medicines.

Japan

Reimbursement decisions are made by the Ministry of Health, Labour and Welfare. After the approval, pharmaceutical companies request to the ministry to add the drug to be added to the positive list for reimbursement by the public insurance system. The ministry will make decisions upon consultation with medical societies. Most of the prescription drugs are covered by the public health insurance scheme, which counts over 15,000 items.

Reimbursement decisions are made no later than 90 days after approval. For reimbursement decisions, any additional documents on evidence are not required besides new drug applications dossier. Nevertheless, since 1992, pharmaceutical companies have been allowed to attach the results of pharmacoeconomic studies to the new drug application dossier.

Sakamaki et al. [14] reported the result of the survey on the dossier with pharmacoeconomic evidence. They picked up all new drugs that were approved from 1997 to 2000 and asked each company if it had submitted economic evaluation data. Among 114 new drugs, 37 (32%) were submitted with economic evaluation data. The proportion did not differ between Japanese companies and foreign companies.

In another study Ikeda and Onozuka [15] surveyed the drugs approved from 2000 to 2002. They revealed that the proportion was reduced to 23%. In this study the reason why companies did not attach such data was also asked. The main reason was that there was no merit to attach pharmacoeconomic data.

Singapore

Subsidies for drugs. Singapore has a Standard Drug List (SDL) that was established in 1979. Standard drugs are defined as clinically relevant and cost-effective drugs that are considered as basic therapies and essential for management of common diseases affecting the majority of patients. Subsidized patients pay $1.40 per item per week for SDL1 drugs (essential first-line drugs) and 50% of the selling price of the SDL2 drugs (relatively more expensive essential drugs). Although there is no subsidy for nonstandard drugs, subsidized patients can pay for nonstandard drugs from their Medisave and/or Medishield (inpatients). If they are unable to pay for these drugs, they can be considered for financial support under Medifund.

An annual call for applications for standard drugs inclusion is made by the MOH to the public institutions. Applicants are required to prioritize their applications before submission (through their respective hospital’s Chairman Medical Board) to the MOH Drug Advisory Committee (DAC). The prioritization criteria include therapeutic gaps, line of therapy, disease prevalence, type of outcome, affordability of the drug to patients, and cost-effectiveness. The DAC evaluates the submissions with the technical assistance of the Pharmaco-economics and Drug Utilization Unit (HSA) (a unit funded by the MOH) and recommends drug preparations that are suitable for inclusion in the SDL. This process is conducted regularly to ensure the continued relevance of the SDL for clinical practice. The DAC also provides guidance to the MOH on rational prescribing and usage of drugs.

Introduction of new technologies. In 2000, the Health Service Development Programme (HSDP) was established by the MOH with the objective of developing new health services and medical capabilities through the funding of, among others, new cutting-edge medical technology, which require a period of evaluation. Since its inception, all proposals for funding under the HSDP have been required to include evidence to support the use of the proposed technology, and this is best achieved by submitting an health technology assessment (HTA) report of the technology.

Role of evidence in policymaking and clinical practice. In addition to the above examples, HTA is also used in policy development. These are most commonly done as rapid reviews, with more comprehensive reviews done if the topic warrants it.

To provide guidance on evidence-based clinical practices for important conditions, the MOH has published 56 clinical practice guidelines (CPG) (including revisions) to date since the first one in 1997. The target audience is primary care doctors. The topics are selected during an annual prioritization exercise involving stakeholders (MOH, professional societies like College of Family Practitioners Singapore, Academy of Medicine, and the Singapore Medical Association). Topics for CPG development are selected based on national priorities in disease management, public health impact, potential number of doctors and patients who can benefit, and utility of guidelines (e.g., condition where there is evidence of effective treatment but wide variation in practice) [16].

CPGs are developed by multidisciplinary expert workgroups through evidence-based methodologies. Drafts are sent to relevant professional societies to build consensus and seek endorsement. CPGs are published, launched, and disseminated to all registered medical practitioners and other relevant professionals. CPGs are freely available online in various formats (PDF, handheld formats). Launches are recorded and slides and speeches are also available online. Patient versions of the guidelines are also published.
The MOH also organizes and carries out training on evidenced-based medicine (EBM) methods and topics in collaboration with external partners. Training on CPG development and critical appraisal workshops have also been organized to promote a culture of evidence-based health care. The ministry also collaborated with the Singapore Medical Journal to publish a quarterly newsletter (i.e., TARGET) that highlights recently published systematic reviews, HTA, CPGs, and EBM topics from elsewhere. As part of the ministry’s effort to raise the profile of EBM and HTA, major international conferences, the Health Technology Assessment International Annual Meeting, and the Cochrane Colloquium are being held in Singapore in 2009.

**Mechanisms, Processes, and Evidence Used in Decisions on Pricing**

**China**

The National Development and Reform Commission (NDRC) has been in charge of the pricing of medical drugs and devices that are included in the drug formularies associated with all publicly funded insurance programs. Products not covered in the drug formularies can be determined freely by market forces. Although drugs included in the state drug formulary list account for 20% of approximately 10,000 available products, they share about 60% to 70% of market sales value.

Drug price regulation is jointly administrated by NDRC agencies at both national and provincial levels. Currently, about 1500 drugs have been classified as category A, and their pricing is determined by the NDRC at the national level. About 800 or 15% of drugs are classified as category B, and their price ceilings are left to the discretion of provincial governments. In 2005, pricing regulatory responsibility for OTC drugs was delegated from the NDRC to provincial pricing bureaus that can set prices according to local health-care priorities and requirements.

There are two primary drug pricing regulations: 1) uniform pricing ceiling applicable to generics of meeting good manufacturing practice (GMP) standard; and 2) “independent pricing policy” for specified pharmaceutical products, largely patented medicines, off-patent originators, domestic primary generics, and subsequent generics of obviously superior quality. In 2001, the NDRC issued regulations, permitting drugs that can demonstrate a better treatment rate at a lower cost than generics or similar drugs to apply for independent pricing under a special pricing system. This system allows companies to request special higher prices if they can show significant safety and efficacy benefits compared with similar drugs. The “independent pricing policy” has played positive roles in motivating manufacturers to improve drug quality and undergo incremental innovation in recent years.

Since 1998, the NDRC has instituted 27 mandatory retail price cuts on over 2000 chemical compounds and 300 TCMs. On average, the price reduction cross therapeutic categories is around 20%. Nevertheless, the excessive pricing cuts did not seem to accomplish the intended goal of reducing the total private out-of-pocket spending in recent years. This is primarily because a uniform pricing cut was encountered by the lack of a comprehensive reform in the rational use of medicine, insurance coverage policy, and the SFDA approval policy for “new” drugs. For example, for each price cut, manufacturers responded with launching more “new” drugs, usually branded generics under changed name, formula, or packaging, whereas “old” drugs were removed from the market because of low profit margins.

With government pricing interventions, how is the average price level of pharmaceuticals in China relative to other countries in Asia? A recent study [17] finds that the average price of all drugs in China is about 35% of developed markets and 55% of Asia/emerging markets. For generics, the relative prices in China are even lower at about 20% to 30% of comparable drugs in selected Organization for Economic Cooperation and Development (OECD) markets.

**Japan**

Prescribed drug prices are determined by the government, based on the opinions of the Central Social Insurance Medical Council (Chu-I-Kyo). The council consists of seven representatives from health-care providers, seven from health-care insurers, and six from public perspective. Medical fee and drug prices are regularly revised every 2 years. Drug price revision is based on the wholesale price survey. All wholesalers and sampled health-care providers are surveyed. The price of each drug is set at the mean wholesale price plus reasonable zone (R-zone). R-zone is thought to cover the reasonable margin for health-care providers to store and dispense drugs. It is currently determined as 2% of the previous price.

For new drugs there are two methods to set base prices. One is based on comparison with a similar drug. The similar drug is chosen by means of similarity in efficacy, pharmacology, chemical structure, medication method, and form. The base price of the new drug is calculated as the daily expenditure will be equivalent to the daily expenditure of the similar drug. It seems reasonable as far as the similar drug is adequately chosen and can be thought to have equivalent efficacy and safety. Nevertheless, if the new drug is more effective than the similar drug, the new drug can be priced higher than the similar drug. It is called “innovative addition” and “useful addition.” Innovative addition is 50% to 100% of the base price, and it is applied when the new drug is developed with innovative idea, shows extremely high efficacy or safety, and contributes to a large improvement in the treatment of the target disease. Useful addition is 5% to 40% and applied when a part of the three criteria for innovative drug is achieved.

The second method is applied when there are no similar drugs to the new drug. In this case the base price will be based on actual costing data submitted by the pharmaceutical company. Costing data include costs of research and development as well as costs of producing and distribution. This rule is just on costing and does not consider the value of drugs.

After the base price for the new drug is determined, the price is adjusted by taking the average price of the drug of the United States, the UK, France, and Germany into account. When the base price of the new drug is calculated as 50% or higher than the average price of those countries or the base price is 25% or lower, the price will be adjusted so that the price difference between Japan and foreign countries will be smaller.

**Singapore**

Singapore does not practice price or profit controls, relying instead on market forces.

**Discussion and Conclusion**

**China**

Under the current health-care reform agenda, the development of a national EDL will be a key component of the state drug policies. The EDL selection criteria would include the population disease prevalence, efficacy, safety, and cost-effectiveness of the medical products. Following the health reform plan, all EDL drugs will be priced under government control, used as the first-line products, and fully paid by the state insurance programs.
The reform effort is also intended to curb the overproduction of generics and to promote a more efficient and systematic production of products. It is expected that the subsequent generics (copies) will be priced on a decreasing scale away from the price of the first generic of that type. Prices for second and third generics must be set at a certain percentage lower than the price of the original generic. Moreover, pharmacoeconomics has been recognized as an economic approach for drug evaluations for both the NDRC pricing and state EDL policy settings.

Japan

After having reviewed the domestic cost-effectiveness evidence, Chu-I-Kyo decided to include smoking-cessation therapy in the coverage list of public health insurance in April 2006 and nicotine patches in June 2006. It was unusual but might encourage the use of economic evaluation for health insurance coverage in Japan.

Those several years, there were some positive movements for spreading pharmacoeconomic studies in Japan. In 2006, education periods for pharmacists were extended from 4 to 6 years in Japan. Some pharmacy schools adopted the pharmacoeconomic courses in the curriculum. The other landscapes can be observed in the new pricing and reimbursement methods for drug approval under discussions in the Japanese government. It has been proposed to the government by the Federation of Pharmaceutical Manufacturers Association of Japan since 2007.

Singapore

Recommendations in relevant CPGs have been used to develop systematic, evidence-based chronic disease management protocols at the national level, i.e., diabetes, lipid disorder, hypertension, stroke, asthma, and chronic obstructive lung disease. These protocols are complemented by clinical data collection to facilitate the monitoring of process compliance by doctors participating in the Medisave for Chronic Disease Management Programme (This program was started in October 6). Patients visiting doctors participating in this program are allowed to use their Medisave to pay for their outpatient visits. Participating doctors are required to report to the MOH the care processes [based on a predetermined list, e.g., HBAic test, eye and foot check, etc.] that they have provided to their patients.] [18] and clinical outcomes (e.g., HBAic and LDL results) [19]. These data are provided back online to GPs comparing their patient demographics and results with other (deidentified) GPs in their region as well as the national aggregate.

As part of the MOH’s effort to ensure appropriate care, health-care institutions and staff are required to conduct regular peer reviews of their standards of care through activities such as pharmaceutical and therapeutics reviews to support rational utilization of drugs. Health-care providers are also monitoring the provision of evidence-based care for other diseases such as acute myocardial infarction (e.g., aspirin on admission/discharge, etc.).

Conclusion

In conclusion, all three countries have established their own mechanisms and processes of market approval, reimbursement, and pricing control, but cost-effectiveness requirements have not been fully introduced yet. Singapore uses pharmacoeconomic evidence for making a reimbursement decision, and some sounds of reforms can be heard in China and Japan toward the future.

The author would like to acknowledge the contributions of Ms. Christina Lim, Deputy Group Director, Health Products Regulation Group, Health Sciences Authority, Ms. Chan Cheng Leng, Director Pharmacovigilance Branch Health Products Regulation Group, Health Sciences Authority, and Dr. Pwee Keng Ho, Deputy Director Health Technology Assessment, Ministry of Health Singapore for the sections on Singapore.

Source of financial support: None.

Gordon G. Liu, Takashi Fukuda, Chien Earn Lee, Vivian Chen, Qiang Zheng, and Isao Kamae have no conflicts to declare.

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