



ELSEVIER

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/vhri

From Regulatory Approval to Subsidized Patient Access in the Asia-Pacific Region: A Comparison of Systems Across Australia, China, Japan, Korea, New Zealand, Taiwan, and Thailand

Greg Cook, PhD*, Hansoo Kim, MSc

Bristol Myers Squibb Australia, Mulgrave, Victoria, Australia

ABSTRACT

Objectives: To compare processes and timings of regulatory and subsidized access systems for medicines across seven jurisdictions within the Asia-Pacific region. **Methods:** A questionnaire was developed focusing on regulatory and health technology assessment-based subsidized access processes and timings in each of the seven surveyant's jurisdictions. **Results:** Australia and Thailand are the only two jurisdictions that formally allow the subsidized access evaluation process to be conducted in parallel with the regulatory evaluation process. Australian, Japanese, Korean, New Zealand, and Taiwanese systems afford broad coverage, whereas Chinese and Thai systems provide limited coverage for medicines under patent. Subsidized access systems for all jurisdictions except Thailand have an associated patient co-payment for each medicine/prescription. The biggest disparity across the study group relates to time from regulatory submission to subsidized access of patented medicines—

ranging from just over 1 year (Japan) to a minimum of 5 years (China). **Conclusions:** There is consistency across the seven jurisdictions studied in relation to regulatory and subsidized patient access processes—that is, regulatory approval is required before subsidized access review; subsidized access coverage is broad; and the cost of medicine subsidization is offset, in part, by patient co-payments. Although local differences will always exist in relation to budget and pricing negotiation, there may be efficiencies that can be applied across systems to improve time to subsidized access. Closer understanding of regulatory and subsidized access systems can lead to best-practice sharing and, ultimately, timely access and better health outcomes for patients.

Keywords: access, Asia-Pacific, HTA.

Copyright © 2015, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.

Introduction

In the Asia-Pacific region, most countries provide access to medicines through government subsidized programs, which range from national tax-funded schemes such as the Australian Pharmaceutical Benefits Scheme (PBS) [1] through to coverage of a specific population such as the Thailand Social Security Scheme for private sector workers [2].

Medicines are traditionally assessed by a regulatory agency such as the New Zealand Medicines and Medical Devices Safety Authority [3] or the Chinese Food and Drug Administration [4] before market authorization. The regulatory process includes an extensive scientific evaluation of the particular drugs' benefit/risk profile and was traditionally the main hurdle before patients could gain access to new medicines. An example of this was the negative list system of South Korea pre-2008, in which only those drugs that were not covered by the Health Insurance Review and Assessment Service were specified [5].

Although Australia has had a cost-effectiveness-based subsidized access process in place after regulatory approval since 1993, formal subsidized access processes in other Asia-Pacific jurisdictions are less than a decade old. Navigating these systems can be as simple as submitting a pricing application, which at the moment is the norm in Japan [6], or as complex as a full-scale societal health technology assessment (HTA) as, for instance, in Taiwan [5]. An unintended consequence of this extra layer of scrutiny is a possible delay in access to medicines for patients because manufacturers now have to clear two hurdles (registration and subsidized access) before they can provide the new drugs to patients.

The aim of this study was to compare and contrast processes and timings of regulatory and subsidized access systems for medicines across the Asia-Pacific region qualitatively. Although the jurisdictions involved in this study have substantially different demographic and economic characteristics, and are in different phases of HTA development and utilization [4], learnings

Conflict of interest: Although Greg Cook and Hansoo Kim are employees of Bristol Myers Squibb Australia, the views presented here are those of the authors and not necessarily those of Bristol Myers Squibb Australia.

* Address correspondence to: Greg Cook, Bristol Myers Squibb Australia, Level2/4 Nexus Crt, Mulgrave, Victoria 3170, Australia.

E-mail: greg.cook@bms.com.

2212-1099/\$36.00 – see front matter Copyright © 2015, International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Published by Elsevier Inc.

<http://dx.doi.org/10.1016/j.vhri.2015.03.013>

from this study may help identify best practice and/or ideas that will ensure timely access to new medicines in the future.

Methods

A total of seven jurisdictions were selected to participate in the survey (Australia, China, Japan, South Korea, New Zealand, Taiwan, and Thailand). The seven jurisdictions are linked by the fact that each uses HTA to assist in decision making specific to subsidized patient access of medicines.

A common template requesting information specific to regulatory and subsidized access processes, timelines, level of coverage, and patient co-payment details was developed and sent out to participating jurisdictions (see [Appendix 1](#) in Supplemental Materials found at <http://dx.doi.org/10.1016/j.vhri.2015.03.013>). The *regulatory process* was defined as the assessment of the risk-benefit profile by the jurisdiction's regulatory body. The *subsidized access process* was defined as the assessment of the value (cost-effectiveness) of a medicine by the jurisdiction's HTA body. The *time taken to pass through the regulatory and subsidized access systems* was defined as time from submission through to registration date and subsidized access date, respectively.

In addition, information specific to the timelines of registration and subsidized access to two new medicines (apixaban for prevention of venous thrombo-embolism [VTE-P] and alogliptin for type 2 diabetes mellitus [T2DM]) was sourced from each jurisdiction. These data were captured to examine whether “real-life” timelines associated with registration and subsidized access of new medicines matched the theoretical timelines specific to each jurisdiction. The two medicines were selected in an attempt to gain information from as many of the seven jurisdictions as possible.

Health economics and outcomes research or market access representatives from Bristol Myers Squibb in individual jurisdictions were asked to complete the questionnaire either from their own knowledge or with the support of local experts. Data obtained were synthesized and rechecked by local experts in HTA to avoid bias or misinterpretations.

The questionnaire included the following items:

1. Name of regulatory body and regulatory evaluation committee.
2. Time frame associated with the registration process.
3. Name of subsidized access body and subsidized evaluation committee.
4. Time frame associated with the subsidized access process.
5. Level of subsidized access coverage.
6. Patient co-payments associated with subsidized access coverage.
7. Registration and subsidized access timelines specific to apixaban for VTE-P and alogliptin for T2DM.

The responses were reviewed by the authors and synthesized qualitatively except for time frames, which were directly compared using nonstatistical methods.

Results

An outline of each of the regulatory and subsidized access systems across the seven Asia-Pacific jurisdictions studied is presented below, followed by a summary comparison.

Australia

Applications for the registration of new medicines and indications are evaluated by the Australian Therapeutic Goods

Administration (TGA), with the standard evaluation process set at 12 months [7]. Before January 1, 2011, a TGA delegate's positive recommendation was required before a sponsor could apply for subsidized access via the PBS; however, as a result of the Australian government's memorandum of understanding with Medicines Australia, submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing new medicines and indications on the PBS can occur in parallel with TGA submissions [8]. The PBAC evaluation process is 17 weeks, with a further 20 weeks built into the system before PBS listing to cover pricing and administrative requirements. Medicines with a high budget impact (i.e. >AU\$20 million incremental cost to the PBS) require Australian government cabinet approval [9] and for these medicines PBS listing times may therefore extend beyond the theoretical 72 weeks minimum time from regulatory application to PBS listing (Fig. 1).

The PBS lists medicines available to be dispensed to patients at a government-subsidized price. The scheme is available to all Australian residents who hold a current Medicare card as well as to overseas visitors from countries with which Australia has a reciprocal health care agreement [10]. A flat-fee patient co-payment exists within the Australian system, with adults currently paying AU \$37.70 (US \$29.39) and concession card holders AU \$6.10 (US \$4.76) per prescription (Table 1) [11].

China

The China Food and Drug Administration falls directly under the State Council of the People's Republic of China, which is the authority of drug regulation in mainland China. China Food and Drug Administration registration of new medicines is required before selection for inclusion within China's two major health insurance programs covered under the Basic Health Insurance Scheme (BHIS): the urban resident basic medical insurance scheme and the new rural cooperative medical system [12]. This medicine selection process for the urban population program occurs every 2 to 4 years, with revision of the formulary dependent on the Ministry of Labor and Social Security decision that it is time for a review [13]. Figure 1 illustrates that the theoretical time from regulatory application to subsidized access in China is greater than in any of the other jurisdictions studied.

The philosophy of the BHIS formulary is to provide basic drug coverage within a cost-containment setting. Because the BHIS is jointly funded by the government, employers, and employees, a patient co-payment does exist for BHIS-listed medicines, although the exact amount depends on the subinsurance system (Table 1).

Japan

The Japanese Pharmaceutical and Medical Devices Agency scientifically reviews new medicines and indications for marketing authorization [14]. Following Pharmaceutical and Medical Devices Agency registration, subsidized access covering all Japanese citizens can be applied for via the National Health Insurance Scheme [6]. The process for National Health Insurance (NHI) listing in Japan can be very quick (8–12 weeks), with Figure 1 illustrating that of the seven jurisdictions studied, Japan has the shortest theoretical time frame from regulatory application to subsidized access (60 weeks).

Depending on the age and employment status of a patient, co-payments in Japan range from 0% through to 30% of the cost of the subsidized medicine (Table 1).

South Korea

Registration of new medicines and indications by the South Korean Ministry of Food and Drug Safety can take 12 to 18 months depending on whether the medicine is a chemical or

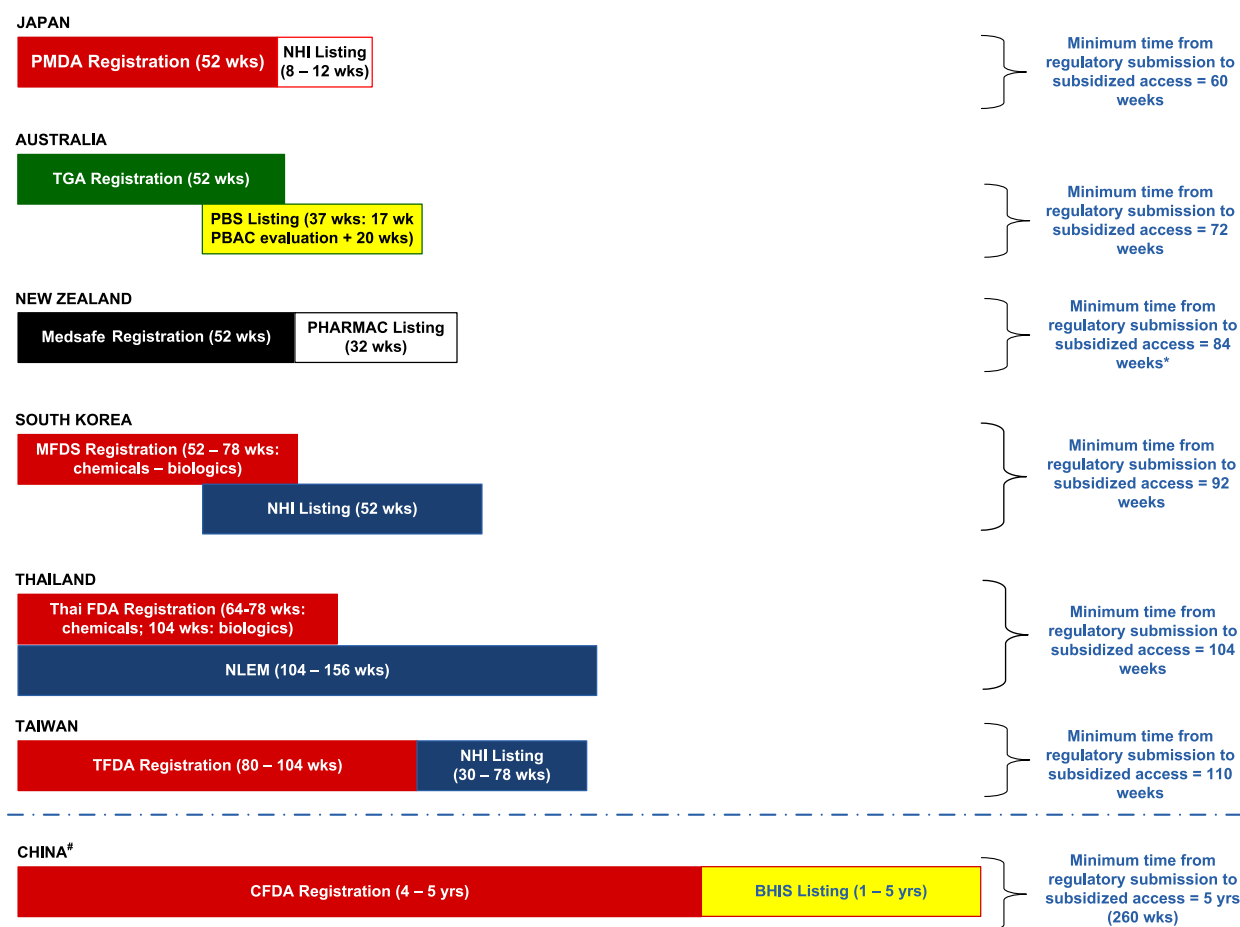


Fig. 1 – Time to progress through regulatory and subsidized patient access systems across Asia-Pacific (Theoretical). CFDA, China Food and Drug Administration; BHIS, Basic Health Insurance Scheme; FDA, Food and Drug Administration; MFDS, Ministry of Food and Drug Safety; NHI, National Health Insurance; NLEM, National List of Essential Medicines; PBS, Pharmaceutical Benefits Scheme; PBAC, Pharmaceutical Benefits Advisory Committee; PHARMAC, Pharmaceutical Management Agency; PMDA, Pharmaceutical and Medical Devices Agency; TFDA, Taiwanese Food and Drug Administration; TGA, Therapeutic Goods Administration. *Indicative only as guidelines (not cited in guidelines). †Current process (August 2014); specific to urban population only.

biologic agent. Following registration, sponsor companies can apply to the Health Insurance Review and Assessment service for subsidized market access for their medicines via the South Korean NHI scheme [15]. Evaluation and time to NHI listing can take an additional 12 months postregistration, although since September 2014, the government now allows subsidized access submissions in South Korea when the review of safety and efficacy of a new drug is positive and before a final regulatory approval decision.

The South Korean system affords broad coverage to 99% of South Korean citizens, with patient co-payments being a percentage component of the cost of the subsidized medicine—for example, 5% for oncology medicines, 10% for medicines to treat rare diseases, and up to 30% for other medicines (Table 1).

New Zealand

Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) is responsible for the regulation of medicines in New Zealand [16]. As with most of the jurisdictions studied in this article, registration of new medicines and indications in New Zealand takes approximately 12 months. Upon registration, sponsor companies can apply to the Pharmacology and

Therapeutics Advisory Committee for subsidized access via the Pharmaceutical Management Agency (PHARMAC). Although guidelines do not stipulate a specific time frame for Pharmacology and Therapeutics Advisory Committee evaluation, theoretically PHARMAC listing can take as little as 32 weeks after Medsafe registration [17].

PHARMAC affords universal coverage of subsidized medicines for New Zealand residents, with patient co-payments at the lower end of the seven jurisdictions studied—at a flat fee of NZ \$5 (US \$3.76) per prescription and free for patients younger than 6 years (Table 1) [17].

Taiwan

New medicines and indications are reviewed and evaluated by the Taiwanese Food and Drug Administration before granting of registration in Taiwan. Depending on the complexity of the application, evaluation and approval can take up to 2 years [18]. Sponsor companies can then submit applications for NHI subsidization. Submissions are evaluated by the Drug Benefit Committee who makes recommendations to the Bureau of National Health Insurance [19]. NHI evaluation and listing can take between 30 weeks and one and a half years.

Table 1 – Comparison of subsidized patient access systems across the Asia-Pacific.

Jurisdiction	Subsidized patient access system	Coverage	Patient co-payment
Australia	Pharmaceutical Benefits Scheme (PBS)	<ul style="list-style-type: none"> • Universal coverage of subsidized medicines for Australian residents 	<ul style="list-style-type: none"> • AU \$37.70 (US \$29.39) (adult) • AU \$6.10 (US \$4.76) (concession)
China	Basic Health Insurance Scheme (BHIS)—urban and rural schemes	<ul style="list-style-type: none"> • Covering urban and rural residents 	<ul style="list-style-type: none"> • Yes (amount depends on the subinsurance system)
Japan	National Health Insurance (NHI) Scheme	<ul style="list-style-type: none"> • Coverage to all Japanese citizens 	<ul style="list-style-type: none"> • 30% • 10% or 20% (elder and preschool child)
South Korea	NHI Scheme	<ul style="list-style-type: none"> • Coverage to 99% of Korean citizens 	<ul style="list-style-type: none"> • 30% • 5% oncology medicines; 10% rare disease medicines
New Zealand	Pharmaceutical Management Agency (PHARMAC)	<ul style="list-style-type: none"> • Universal coverage of subsidized medicines for New Zealand residents 	<ul style="list-style-type: none"> • NZ \$5 (US \$3.76) • Free (younger than 6 y of age)
Taiwan	National Health Insurance Administration (NHIA)	<ul style="list-style-type: none"> • Coverage to 99.9% of Taiwanese citizens 	<ul style="list-style-type: none"> • NTD20 (US \$0.64) for medicines < NTD100 (US \$3.19) • Add NTD20 (US \$0.64) per additional NTD100 medication cost • Cap for co-payment at NTD200 (US \$6.37)
Thailand	National List of Essential Medicines	<ul style="list-style-type: none"> • Coverage of generics and cost-effective patented medicines for Thai citizens 	<ul style="list-style-type: none"> • No co-payment

Note. Foreign exchange rates: sourced March 3, 2015. NTD, New Taiwanese dollar.

The NHI provides for broad coverage of 99.9% of Taiwanese citizens with a scaled patient co-payment in place. Currently, the patient co-payment is New Taiwanese dollar (NTD) 20 (US \$0.64) for medicines up to NTD100 (US \$3.19), with an additional NTD20 required for every additional NTD100. A co-payment cap is set at NTD200 (US \$6.37) (Table 1).

Thailand

Registration of new medicines and indications in Thailand occur via the Thailand Food and Drug Administration [2]. Evaluation and registration can take between 1 and 2 years depending on whether the medicine is a chemical or biological agent. Subsidized access submissions are made to the Health Intervention and Technology Assessment Program for approval to be placed on the National List of Essential Medicines [19]. Although this process can take between 2 and 3 years to complete, it can be done in parallel with the regulatory process, thereby reducing overall time to subsidized market access (Fig. 1). The Thailand subsidized access system covers generic medicines and patented medicines that have been proven cost-effective for all Thai citizens and is not associated with a patient co-payment (Table 1).

Summary

Time to progress through regulatory and subsidized access systems varies across the seven Asia-Pacific jurisdictions studied (Fig. 1), with Australia and Thailand the only jurisdictions that formally allow the subsidized access evaluation process to be conducted in parallel with the regulatory evaluation process. Note that a subsidized access submission in Korea can occur 2 months before the finalization of registration under exceptional circumstances.

Figure 1 also demonstrates that Japan has the shortest “theoretical” time from regulatory submission to subsidized market access for medicines at 60 weeks, followed by Australia (72 weeks), New Zealand (84 weeks), South Korea (92 weeks),

Thailand (104 weeks), Taiwan (110 weeks), and China (up to 5 years). A review of recent examples of medicines passing through regulatory and subsidized access systems across Asia-Pacific generally confirmed the order and theoretical timings outlined in Figure 1.

Table 2 illustrates that with respect to the medicine apixaban for the prevention of venous thromboembolism, Australia had the shortest time from registration to subsidized access (21 weeks), followed by Taiwan and South Korea (42 and 60 weeks, respectively). Note that complete data for China, Japan, New Zealand, and Thailand were not available. Data sourced specific to the medicine alogliptin for the treatment of T2DM demonstrated that Japan had the shortest time from registration to subsidized access (9 weeks), followed by Australia and South Korea (13 and 30 weeks, respectively). Again not all jurisdictions could provide complete data, with alogliptin not yet subsidized in China, New Zealand, Taiwan, and Thailand at the time of research.

Discussion

A review of the regulatory and subsidized patient access processes across seven Asia-Pacific jurisdictions was conducted in an effort to not only learn about the nuances of each system but also look for potential examples of best-practice that could be considered by individual jurisdictions.

Although regulatory systems in each of the jurisdictions studied are well established, variation exists with regard to the extent to which HTA plays a role in the subsidized access evaluation process. Australia was the first country to directly link HTA economic evaluation to subsidized access to medicines, with the Australian government from 1993 requiring the PBAC to consider the cost-effectiveness of all new drugs for which PBS subsidy was being sought. [20] New Zealand followed soon after, with HTA evaluation becoming part of the subsidized access decision-making process relatively recently in South Korea (2006), Thailand (2007), and Taiwan (2007) [21,22]. Although HTA in

Table 2 – Time to progress through subsidized patient access systems across Asia-Pacific (practical examples: apixaban for VTE-P and alogliptin for T2DM).

Jurisdiction	Date of registration	Date of subsidized access	Time from registration to access (wk)
<i>Apixaban for VTE-P</i>			
Australia	July 2011	January 2012	21
Taiwan	August 2013	June 2014	42
South Korea	November 2011	January 2013	60
New Zealand	June 2013	NA	60+
Thailand	November 2012	NA	91+
<i>Alogliptin for T2DM</i>			
Japan	April 2010	June 2010	9
Australia	September 2013	December 2013	13
South Korea	May 2013	January 2014	30

NA, not applicable/available; T2DM, type 2 diabetes mellitus; VTE-P, prevention of venous thromboembolism.

China and Japan can be traced back to the 1990s, it has yet to find as firm a footing as established HTA jurisdictions. Recent commitments from governments, however, may see HTA increase in importance in these jurisdictions [23].

In general, there is consistency across the seven Asia-Pacific jurisdictions studied in relation to regulatory and subsidized patient access processes. Regulatory approval is required before subsidized access review; subsidized access coverage is broad within the Australian, Japanese, Korean, New Zealand, and Taiwanese systems; and the cost of medicine subsidization is offset, in part, by patient co-payments in all subsidized access systems except for Thailand.

The biggest disparity across the study group relates to the time taken from regulatory submission to subsidized access—with times ranging from just over 1 year to greater than 5 years. Although local differences will always exist in relation to final budget and pricing negotiation, there may be technical and administrative efficiencies that can be applied across systems to improve time to subsidized access—a key and growing focus for patients and advocacy groups.

Clearly, parallel regulatory and subsidized access evaluation is one area in which time efficiencies can be gained. Currently, Australia, Thailand, and South Korea allow for parallel processing. In Australia, any risk associated with the regulatory agency not granting market authorization is offset by 1) the sponsor company paying a cost-recovery fee to cover resources specific to the subsidized access evaluation and 2) agreement that the outcome of the assessment by the subsidized access agency will not be made publicly available until the regulatory agency has made a decision.

Another potential way to reduce time to subsidized access is to consider how to remove duplication from regulatory and subsidized access assessments. A recent collaboration between the European Medicines Agency and the European network for Health Technology Assessment was established and is examining ways of improving the contribution of regulatory assessment reports to the assessment of medicinal products by HTA bodies [24]. Although the assessment of relative effectiveness should remain the remit of subsidized access agencies, there are data and review efficiencies that can be implemented. Recommended outcomes from collaborations such as these could be used globally to improve communications within sponsor companies, expand dialogue between regulators and HTA bodies, support policymaker decisions, and improve time to subsidized access for patients in the future.

A potential limitation of this study relates to the data gaps seen in the practical examples looking at time to subsidized access for the two selected medicines (apixaban for VTE-T; alogliptin for T2DM). Although intended to test the theoretical time frames to subsidized access across jurisdictions (displayed

in Fig. 1), the medicines selected had not been granted subsidized access in all jurisdictions studied. For the jurisdictions where data were available, the timing of subsidized access matched the jurisdiction order in Figure 1. A follow-up review at a later time point and/or investigation of additional medicines will provide further clarity.

In conclusion, although regulatory systems are well established, formalized subsidized access systems are relatively new, with HTA processes developing at uneven speeds [25]. Closer understanding of different regulatory and subsidized access processes within Asia-Pacific will allow for best-practice cross-pollination, optimal and timely subsidized access, and, ultimately, better outcomes for patients.

Acknowledgments

We acknowledge and thank the following colleagues who provided data and insight specific to their jurisdiction: Scott Brydon (Australia/New Zealand); Patrick Chou and Oscar Liao (Taiwan); Hyeyeon Jung, Su-Kyoung Ko, and Yu-Ri Lee (South Korea); Toshihara Kunihira (Japan); Yanjun Zang and Zhiliu Tang (China); and Jiraboon Tosanguan (Thailand).

Source of financial support: The authors have no other financial relationships to disclose.

Supplementary Materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at <http://dx.doi.org/10.1016/j.vhri.2015.03.013> or, if a hard copy of article, at www.valueinhealthjournal.com/issues (select volume, issue, and article).

REFERENCES

- [1] Sansom L. The subsidy of pharmaceuticals in Australia: processes and challenges. *Aust Health Rev* 2004;28:194–205.
- [2] Ngorsuraches S, Meng W, Kim B-Y, et al. Drug reimbursement decision-making in Thailand, China, and South Korea. *Value Health* 2012;15 (Suppl):S120–5.
- [3] Ragupathy R, Aaltonen K, Tordoff J, et al. A 3-dimensional view of access to licensed and subsidized medicines under single-payer systems in the US, the UK, Australia and New Zealand. *Pharmacoeconomics* 2012;30:1051–65.

- [4] Yoongthong W, Hu S, Whitty JA, et al. National drug policies to local formulary decisions in Thailand, China and Australia: drug listing changes and opportunities. *Value Health* 2012;15(Suppl):S126–31.
- [5] Yang B. The future of health technology assessment in healthcare decision making in Asia. *Pharmacoeconomics* 2009;27:891–901.
- [6] Liu GG, Fukuda T, Lee CE, et al. Evidence-based decision-making on medical technologies in China, Japan, and Singapore. *Value Health* 2009;12(Suppl):S12–7.
- [7] Australian Therapeutics and Goods Administration. Australian prescription medicines registration process. Available from: www.tga.gov.au/prescription-medicines-registration-process. [Accessed November 28, 2014].
- [8] Australian Government and Medicines Australia. Memorandum of understanding with Medicines Australia. Available from: <http://www.pbs.gov.au/info/industry/useful-resources/memorandum>. [Accessed November 28, 2014].
- [9] Australian Government, Department of Health. The PBS. Available from: <http://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/pbac-outcomes>. [Accessed March 3, 2015].
- [10] Australian Government, Department of Health. About the PBS. Available from: www.pbs.gov.au/info/about-the-pbs. [Accessed November 28, 2014].
- [11] Australian Government, Department of Health. Fees, patient contributions and safety net thresholds. Available from: <http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee>. [Accessed November 28, 2014].
- [12] Wang X, Zheng A, He X, et al. Integration of rural and urban healthcare insurance schemes in China: an empirical research. *BMC Health Serv Res* 2014;14:142. Available from: <http://www.biomedcentral.com/1472-6963/14/142>. [Accessed November 28, 2014].
- [13] ISPOR. ISPOR global health care systems road map—China Mainland. Available from: www.ispor.org/HTARoadMaps/China.asp. [Accessed November 28, 2014].
- [14] Pharmaceutical and Medical Devices Agency Japan. Regulations and procedures. Available from: www.pmda.go.jp/english/service/regulation.html. [Accessed November 28, 2014].
- [15] Bae EY, Lee EK. Pharmacoeconomic guidelines and their implementation in the Positive List System in South Korea. *Value Health* 2009;12(Suppl):S36–41.
- [16] New Zealand Medicines and Medical Devices Safety Authority. Welcome to Medsafe. Available from: www.medsafe.govt.nz/. [Accessed November 28, 2014].
- [17] New Zealand Pharmaceutical Management Agency. PHARMAC. Available from: www.pharmac.health.nz. [Accessed November 28, 2014].
- [18] Liu YM, Yang YH, Hsieh CR. The determinants of the adoption of pharmaceutical innovation: evidence from Taiwan. *Soc Sci Med* 2011;72:919–27.
- [19] Jirawattanapaisal T, Kingkaew P, Lee T-J, et al. Evidence-based decision-making in Asia-Pacific with rapidly changing health-care systems: Thailand, South Korea, and Taiwan. *Value Health* 2009;12(Suppl):S4–10.
- [20] Australian Government, Department of Health. The PBS. Available from: <http://www.pbac.pbs.gov.au/information/rationale-and-basis-for-economic-evaluation.html>. [Accessed March 3, 2014].
- [21] Sivalal S. Health technology assessment in the Asia Pacific region. *Int J Technol Assess Health Care* 2009;25(Suppl. 1):196–201.
- [22] ISPOR. ISPOR global health care systems road map—Taiwan. Available from: <http://www.ispor.org/htaroadmaps/Taiwan.asp>. [Accessed March 3, 2015].
- [23] DAI. The payer/reimbursement environment in Japan: present and future. Available from: <http://www.diahome.org/~media/15404CBD3C934077AD32285E2D58DC14.ashx>. [Accessed March 3, 2015].
- [24] Berntgen M, Gourvil A, Pavlovic M, et al. Improving the contribution of regulatory assessment reports to health technology assessments—a collaboration between the European Medicines Agency and the European network for Health Technology Assessment. *Value Health* 2014;17:634–41.
- [25] WHO/HAI project on medicine prices and availability. Available from: http://www.haiweb.org/medicineprices/05062011/HTA_final_Aug2013.pdf. [Accessed March 3, 2015].