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

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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 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.

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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).