

MARKET WATCH

Economic Evaluation And Pharmaceutical Reimbursement Reform In South Korea's National Health Insurance

South Korea has taken bold steps to alleviate the cost pressures that new drugs are putting on its health system.

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ABSTRACT: South Korea's National Health Insurance recently announced a reform in pharmaceutical reimbursement, with the purpose of increasing rational resource use in drug spending. The new policy aims to take the cost-effectiveness and budget impact of newly introduced drugs into account in payment decisions. If the policy is implemented, South Korea will be the first Asian country to officially adopt economic evaluation as a tool for resource allocation in health care. This paper looks at the background, objectives, expected outcomes, potential issues, and resulting trade conflict regarding use of economic data in drug reimbursement decisions in South Korea. [*Health Affairs* 27, no. 1 (2008): 179–187; 10.1377/hlthaff.27.1.179]

THE MOST NOTICEABLE change in the health care system of the Republic of Korea (South Korea) during the past five decades was the establishment of the National Health Insurance (NHI) system in 1989. The NHI system was implemented in stages over twelve years, starting with the first social insurance program for corporate employees in 1977. Each stage of implementation was achieved with little political, economic, or social resistance, because the expansion of health insurance coverage was a popular issue that enjoyed strong political support.

Successful development of NHI, however, has involved costs. With the expansion of coverage, consumers' demand for and expectation of high-quality health care have been contin-

ously increasing, placing heavy financial pressures on the system. NHI began running an annual deficit in 1997, and annual deficits developed into a cumulative deficit in 2001.

Faced with a cumulative deficit, South Korean health authorities made tackling this problem a national priority. Various efforts were made to reduce or eliminate the deficit (with the cumulative deficit erased in 2004), while reforms of various kinds at the system level have been pursued to establish long-term financial stability. One such reform by the Ministry of Health and Welfare and the NHI system concerns use of economic data in decisions regarding payment for newly introduced medical technologies. Because a large portion of rising NHI spending is attributable to extensive use of new medical technologies,

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which are more often cost-increasing than cost-saving, use of economic data in payment decisions will contribute to efforts that seek to make decisions more cost-effective and help produce more health from existing spending. Pharmaceuticals are the first area in which this new policy is to be implemented.

With this implementation, South Korea will become the first Asian country officially to adopt economic evaluation as a tool for resource allocation in health care. It would be of interest to other countries to observe how such a policy could be prepared, processed, and brought to contend with the challenges posed by stakeholders. By looking at the background, objectives, expected outcomes, potential issues, and resulting trade conflict regarding the use of economic data in NHI drug reimbursement decisions, we hope that a meaningful lesson can be conveyed based on the South Korean experience.

Current South Korean Health Care System And NHI

NHI is the central organizing mechanism of the South Korean health care system, through which resources flow among the government, consumers, corporations, and service providers. Currently, 97 percent of Koreans are the beneficiaries of NHI. Health care for the remaining 3 percent, the poorest members of society, is covered by the tax-financed Medical Protection Program. This remarkable achievement of extending coverage to 100 percent of the population in a relatively short period was made possible by the continuously growing per capita income and political democratization during the past three decades.¹

■ **Choice of providers.** In most health service delivery situations, patients are given a choice of hospitals and clinics. They can choose any type of service provider with little constraint. To establish patient referral channels, regulations were introduced in 1989 to partially restrict the choice of providers available through NHI. However, the regulations were not enforced by the hospitals because they feared the loss of revenues; therefore, most patients do not abide by these rules.

■ **Financing.** Providers are paid on a fee-for-service (FFS) basis for services covered by insurance. These fees are paid in part by the National Health Insurance Corporation (NHIC), with the remainder covered by patients' out-of-pocket payments (both deductibles and copayments). NHI, in turn, is financed by premium contributions paid by consumers and employers, along with government subsidy provided by tax revenues.

■ **Dominance by the private sector.** The work of health care delivery is done mostly by the private sector. The private sector, which was dominant in South Korea before the insurance plans were introduced, has continued to grow with the increase in per capita income and the expansion of health insurance coverage. Health care providers are classified into general hospitals, local hospitals, and clinics. In 1999, only 20 percent of all general hospitals and 7 percent of all local hospitals were public; clinics were 100 percent private. There were 7.1 hospital beds per 1,000 Koreans, 87 percent of which were in private hospitals and clinics.² This picture remained largely the same as of 2006.

■ **New medical technologies.** New medical technologies are abundant in South Korea. A report by the Organization for Economic Cooperation and Development (OECD) on per capita possession of key medical equipment shows that among member countries, South Korea is second in computed tomography (CT) scanners, eighth in magnetic resonance imaging (MRI) scanners, third in lithotripters, sixth in mammography, and fifth in hemodialysis.³ The country had more than forty positron emission tomography (PET) scanners as of 2005. It is definitely among the world's leaders in new technology adoption.

NHI Financial Sustainability And Drug Spending: Impetus For A New Initiative

■ **NHI spending: a somber picture.** The financial sustainability of NHI is not promising. Total insurance spending grew about 20 percent annually from 1990 to 2005, mostly because of rising treatment costs. These in-

creases can be explained by several factors, some demand-driven and some supply-driven: expansion of coverage, fee increases exceeding consumer price increases, an aging population, and aggressive use of new technologies. However, the most important factor has been use of the FFS payment method, which structurally ensures that the system's resource requirements are open-ended. The natural consequence of rising treatment costs is NHI's financial deficit (Exhibit 1).

The NHI system has run an annual deficit each year, beginning in 1997, with the size of the annual deficit continuously increasing until 2001, the first year in which NHI had a cumulative deficit. Although a cumulative deficit had been projected for 2003, it arrived earlier than expected because of the abrupt physician and pharmacist fee increases at the end of 2000.⁴ The cumulative deficit moved South Korean health authorities to make the financial stability of NHI a national priority. Various measures were taken to reduce or eliminate the deficits, including greater government contributions from general tax revenues, a newly introduced cigarette tax, higher premiums, control of medical fees reimbursed to providers, and stricter monitoring of fraud in reimbursement claims. The annual deficit declined in 2002, and annual surpluses

in both 2003 and 2004 helped erase the cumulative deficit by December 2004.

However, as long as the FFS reimbursement mechanism, dominance of the profit-seeking private sector, lack of referral network, and the limited management of new medical technologies all remain as they are, the long-run financial outlook for NHI is somber.

■ **Drug spending: an area for rational allocation.** Facing such a dim long-run financial outlook, South Korean health authorities and researchers looked into various ways to maintain financial sustainability and to allocate limited NHI resources rationally. Rising drug spending was one area examined (Exhibit 2). Over the four-year period 2001–2005, pharmaceutical spending in nominal figures nearly doubled, and real spending increased 50 percent. The appropriateness of drug spending, which accounts for more than one-quarter of total NHI outlays (more than 29 percent in 2005), had never been seriously questioned at any level. These rapidly rising costs have led policymakers to consider pharmaceutical reimbursement reform. The health authority therefore contemplates use of economic data (in terms of cost-effectiveness and budget impacts) in deciding whether to include a particular drug item in the reimbursement list and how to determine its pricing.

EXHIBIT 1
Trends In The Financial Status Of South Korea's National Health Insurance (NHI), In Billions Of Korean Won, 1990–2005

	1990	1991	1992	1993	1994	1995	1996	1997
Revenue	2,432	3,269	3,774	4,199	4,711	5,614	6,631	7,554
Expenditure	2,164	2,487	2,967	3,458	3,968	5,060	6,446	7,766
Annual balance	268	782	807	741	743	554	185	-212 ^c
Accumulated surplus ^a	- ^b	- ^b	- ^b	3,432	3,926	4,120	4,002	3,785
	1998	1999	2000	2001	2002	2003	2004	2005
Revenue	8,230	8,892	9,976	12,049	14,405	17,567	19,535	21,237
Expenditure	8,775	9,585	10,919	14,244	14,913	16,097	17,474	20,146
Annual balance	-545 ^c	-693 ^c	-943 ^c	-2,195 ^c	-508 ^c	1,479	2,061	1,091
Accumulated surplus ^a	3,036	2,243	919	-1,811 ^c	-2,572 ^c	-1,492 ^c	76	1,255

SOURCE: National Health Insurance Corporation, *Statistical Yearbook 2005* (Seoul: NHIC, 2006).

^a Accumulated surplus reflects surplus in cash flows, not including NHIC-holding asset values.

^b Data not available.

^c Deficit.

EXHIBIT 2
Trends In Pharmaceutical Expenditure In The South Korean National Health Insurance (NHI), In Billions Of Korean Won, 2001–2005

	2001	2002	2003	2004	2005
Total expenditure	4,180	4,801	5,583	6,354	7,229
Percent of total NHI outlay	23.5%	25.2%	27.2%	28.4%	29.2%
Real expenditure ^a	4,180	4,676	5,250	5,766	6,388
Index of real	100	112	126	138	153

SOURCE: National Health Insurance Corporation, *Statistical Yearbook 2005* (Seoul: NHIC, 2006).

^a Constant price (2001 Consumer Price Index = 100).

Issues With Reimbursement Of Drugs Under NHI

The NHI's reimbursement of drugs can be characterized by two conspicuous features: (1) a large number of drugs on the reimbursement list, and (2) rapid introduction of new drugs into insurance coverage.

■ **Huge reimbursement list.** Almost all of the drugs that receive market approval by the Korea Food and Drug Administration are automatically listed as insurance-reimbursed drugs. Drugs' cost-effectiveness and budget impacts are rarely taken into account in reimbursement decisions. As a result, more than 21,000 drugs are listed on the NHI reimbursement list, a figure that stands in stark contrast to the 3,000–8,000 drugs in the insurance formularies of most OECD countries.⁵ With a long list of many substitutable drugs in a treatment category, a large number of local pharmaceutical companies, which are mostly small and medium-size, heavily compete for product promotion and market sales, often using unfair (and sometimes illegal) promotion and sales strategies. There are more than 600 pharmaceutical companies, most of which spend only a minor proportion of their total revenues for research and development (R&D). Costs incurred by various promotional activities may be passed on to both consumers and NHI in higher prices.

■ **Early adoption of new drugs.** Another aspect of NHI's drug reimbursement is the very early adoption of new drugs into the South Korean market (Exhibit 3). In 2003, three new Korean-made drugs (the number of

countries that adopted these is noted as "0" in Exhibit 3) were reviewed by the South Korean NHI. NHI was second in the world in reviewing twenty-five new drugs (out of sixty-one, 41.0 percent), third in reviewing sixteen products (26.2 percent), and fourth in reviewing eleven products (11.7 percent), and so on.⁶ In other words, more than 67 percent of new drugs reviewed by NHI in 2003 were drugs that South Korea reviewed second and third in the world. A picture was similar for 2004, although the number of new drugs reviewed was lower.

■ **Drug-pricing formula.** The drug-pricing formula of NHI uses A7-country (United States, United Kingdom, France, Japan, Germany, Italy, and Switzerland) prices for new drugs recognized as "innovative" and a relative pricing scheme for other new drugs. In principle, A7-country prices are the starting point. This leads to the concern that with few countries adopting a certain new drug, not enough pricing and clinical data are available to guarantee reasonable pricing of the corresponding drug in Korea. For example, for the twenty-five new drugs in 2003, we could find only one A7 price available, because only one of the A7 countries had adopted the drug for reimbursement. The South Korean price of each of those twenty-five drugs had to be assessed based on a single A7 price as a reference.

Consequently, early adoption of newly introduced drugs could be seen as a problem from the current pricing perspective. Moreover, drugs are entered on the reimbursement list with little consideration of their budget

EXHIBIT 3
Introduction Of New Drugs Into South Korean National Health Insurance (NHI)
Review, 2003–2005

	Total	Officially adopted by number of A7 countries ^a			
		0	1	2	3-7
2003					
Number	61	3	25	16	17
Percent		4.9	41.0	26.2	27.9
2004					
Number	50	1	19	11	19
Percent		2.0	38.0	22.0	38.0
2005					
Number	50	2	14	16	18
Percent		4.0	28.0	32.0	36.0

SOURCE: Health Insurance Review Agency, 2006.

^aNumber of advanced seven (A7) countries that have adopted the submitted drug.

impact or cost-effectiveness. Under these circumstances, the value for money could hardly be optimized in drug spending. Researchers argue that the NHI reimbursement policy needs to be revised to provide rational use of a drug budget, especially given the country’s increasingly constrained resource availability. Rational use would encompass (1) cost-effective use of resources, and (2) making decisions based upon value-for-money considerations.

Reform In Pharmaceutical Reimbursement

■ **Recent practice.** In December 2001, when the NHI Act was amended, new “Guidelines for Determining and Adjusting New Medical Technologies” were announced. These stipulated use of economic evaluations for decisions on pricing, relative values, and the extent of insurance coverage of new medical technologies, encompassing pharmaceuticals, equipment, and diagnostic technology.

Although this law has been in existence since 2001, it has not been implemented, for several practical reasons. First, there were few professionals with experience in using economic evaluation and limited scholarship on this topic in South Korea. Second, unsatisfactory or incomplete evaluation methods and guidelines made it difficult to move ahead

with the use of economic evaluation in practice. Third, government authorities lacked the capacity to judge whether the submitted economic data were appropriate. Last, corporations needed to develop the capacity to conduct research using economic evaluation.

In November 2004 several new members and an economist chairperson joined the Ministry of Health and Welfare’s Drug Pricing and Reimbursement Committee (DPRC), the decision-making body with respect to reimbursement. Since then, a somewhat different perspective has been adopted. The new DPRC looked into economic evidence in nearly every decision, and changes in decisions became evident in 2005 and 2006. The number of new drugs approved in 2005 declined sharply.⁷ For example, of fifty new drugs submitted for NHI reimbursement in 2005, the initial decisions were the following: thirty-one new drugs were recommended (62 percent), fourteen were rejected (28 percent), and five decisions were postponed pending receipt of further information (10 percent). Among the thirty-one recommended drugs, some were “recommended at price” and others were “recommended at lower price.” The five pending cases included some that required supplementary economic data. Of the fourteen rejected drugs, six were rejected because of “health outcomes inferior

to existing comparators,” and eight were because of “economic efficiency too low.” As of January 2006, five of eight drugs that had been rejected for economic reasons had been resubmitted by the manufacturers with lowered prices and were accepted after repeated reviews.

Submission of economic data is still voluntary, because decisionmakers often look at economic data for fear of receiving unfavorable decision on their applications for reimbursement. However, many companies feel pressure to submit economic data.

■ **Official reform under way.** With the objective of seeking appropriateness in rising drug spending, based on the NHIC Act, use of economic data in drug reimbursement decisions has been seriously pursued by the health authority. To review the cost-effectiveness and budget impacts of newly entering drugs, the Health Insurance Review Agency (HIRA) in 2005 prepared the South Korean version of pharmacoeconomic guidelines.⁸ These guidelines provide drug companies with instructions on how to prepare economic data before submitting a drug for reimbursement and pricing. Their more specific objective is to give more consideration to cost-effectiveness in adopting new drugs into the health insurance domain.

In drawing up the guidelines, HIRA invited expert reviews, held public hearings, and held a parliamentary discussion session in the first half of 2006. The new policy of using economic data in drug reimbursement decisions was publicly announced in May 2006 under the heading “Positive List System (PLS).” The PLS policy will be legally enforced beginning in January 2008. Unlike the previous negative system that specified which drugs were not covered by the insurance, the PLS lists covered drugs with economic evaluation as one of the selection criteria.

■ **Expected outcome.** Although decisionmakers in the South Korean government claim that the purpose of using economic data for drug reimbursement decisions is to cut spending, it is unclear whether drug spending in real terms will be reduced. Experiences from early

adopters of economic evaluation (Australia, Canada, and the United Kingdom) indicate that a spending cut might not be realized. Rather, Korean researchers in the field agree that the primary objective is to achieve more rational use of scarce health care resources. As in other countries, South Korea’s resource scarcity is ever increasing because of growing consumer demand and new technologies.

An emphasis on cost-effectiveness and use of scarce resources for greater value will make consumers better off as they gain access to more effective pharmaceuticals, within a given budget. Population health will be better in the long run as a result. By considering the cost-effectiveness of drugs, the insurance authority pursues maximum health outcomes for a given set of resource constraints. Scarce financial resources will be allocated more efficiently in the end.

For pharmaceutical companies, submitting economic data will mean an additional financial burden for data preparation and a prolonged period of approval/reimbursement decision making. However, there will be a long-run efficiency gain for the firms, brought about by healthy competition in products’ prices and outcomes (effectiveness). Producing a better product with improved outcomes through R&D will become a key issue for firms. The South Korean drug industry will improve overall since only efficient firms will survive, and there will be less reliance on undesirable methods of product advertising and promotion. If the government regards growth of the pharmaceutical industry as a strategy for a prosperous national economy in the twenty-first century, use of economic data for reimbursement decisions will contribute to such a national goal in the long run.

Key Issues Facing This Reform

A proper data-submission guideline is a necessary condition for successful implementation of the proposed reform, but hardly a sufficient one. Experiences from the DPRK’s 2005–2006 decisions using submitted economic data reveal a number of key issues to be considered. Furthermore, as the policy has be-

come an important agenda item in recent U.S.-Korea free-trade agreement (FTA) negotiations, South Korean policymakers have to consider how to minimize the FTA's influence on policy contents. The following issues have emerged.

■ **Interpretation of cost-effectiveness results.** In countries that use economic evaluation, there seems to be no officially announced "threshold" of incremental cost-effectiveness ratio for decision making.⁹ In the

case of the U.K. National Institute for Health and Clinical Excellence (NICE) and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, the known ranges of cost-effective or cost-ineffective are, in fact, retrospectively drawn. Some East European countries tend to set a threshold based on per capita GDP levels. Ewa Orlewska

and Piotr Mierzejewski, based upon international experiences with accepted cost-utility ratios, suggest a ratio of 0.7–2.3 times per capita gross domestic product (GDP) as a reference range. This is based on the notion that there may be a linear relationship between GDP and willingness to pay for an additional quality-adjusted life-year (QALY).¹⁰ Is this notion acceptable in the case of South Korea? If not, how can we set a range of incremental cost-effectiveness ratios for decision making? Although there are some objections to specifying such a threshold, South Korea might need some kind of criteria for these decisions. What would they be?

■ **External validity of clinical data.** Effectiveness and efficacy data from one's own population setting are usually not available. It is also difficult for a party to carry out separate clinical experimentation to get such data from its own people. Under these circumstances, the responsible party (government, research institute, or pharmaceutical company) often relies on foreign outcome data for domestic economic evaluation data construction. However, it would not be safe to use foreign out-

come-related clinical data without modifications, considering possible variations stemming from genetic differences. Differences in medical practice patterns among countries would also result in a different scale of effectiveness. To circumvent this difficulty, the South Korean pharmacoeconomic guidelines recommend the following to analysts: First, compare foreign data with local clinical and epidemiological data to cross-check for data transferability; and second, solicit expert

opinions when published clinical or epidemiological data are not available. However, under the highly likely constraints that sources of local epidemiological data are not well secured, or expert opinions are hardly generalizable, would this secondary-source approach be a suitable way to get closer to true local effectiveness and efficacy in-

formation? Could we to some degree overcome outcome variations attributable to varying genetic, geographic, cultural, and medical practice patterns through such means?

■ **Long-term health outcomes.** It is evident that having reasonable health outcome data is an a priori condition for preparing sound economic evaluation data. However, a constraint one often faces is the lack of final intended outcome data, which often requires long-term follow-up. To estimate final outcomes, one often uses modeling techniques. However, information such as transition probabilities is often lacking, thus forcing one to rely on various assumptions, which can mean a high level of uncertainty in estimated health outcomes.

Australia requests that the industry do preliminary economic evaluation (based on comparative randomized trials) in principle and do modeled economic evaluation, if necessary, thereafter. To reduce the level of uncertainty with modeling, would it be better (or necessary) to ask the industry to perform and submit both preliminary and modeled economic evaluation? This could be too burdensome for

“Economic evaluation studies in most Asian countries now use Western tools with no changes in preference measures.”

the industry. However, if a fair judgment with lowered uncertainty is a good thing for both the health system and the industry, should such a requirement be considered?

■ **Measurement of preferences.** Because most new drugs target improving quality of life as an ultimate outcome, cost-utility analysis is recommended as the base analysis. However, quality of life is affected by one's preferences, and preferences in turn are influenced by socioeconomic and cultural factors. For technical assistance in measuring utility, tools such as EQ-5D (Euro quality of life) and HUI (Health Utility Index) are often used. However, because these tools have mostly been developed in Europe and North America, they may fail to reflect Asian cultural preferences, even after the reliability and validity of the questionnaires for Asians or certain Asian populations have been tested. In other words, for a specific health state, Asian preferences may differ from European or American preferences. Economic evaluation studies in most Asian countries now use the Western tools with no changes in preference measures. The corresponding utility estimates could therefore be a misleading representation of Asian preference values. How can we advise (or give instructions to) the responsible party (the industry or research units) to estimate preferences for quality of life correctly, unless we develop our own tools?

■ **Strengthening capacity for reviewing submitted data.** Reviewing capacity has been built up during the past decade in South Korea, producing experts with health economics (subspecialty in economic evaluation) degrees from universities. Most of these people are working at economic evaluation-related jobs either in government or in industry. The experts in government and in academe played a pivotal role in setting up the policy framework, including the South Korean guidelines. However, the health authority needs to increase the capacity to review submitted documents. According to the DPRK's experience over the past few years, the issue seems to be twofold: The system needs a greater number of review experts (in government or academe, or

both) and needs to reduce the variation among reviewers' ability. The South Korean health authority has identified this as an issue and is working to improve the situation. For example, HIRA recently developed a fifteen-point checklist for every reviewer to follow in the review process, with the objective of ensuring that all important review aspects are considered and are done so consistently. The question is whether this measure is sufficient in ensuring the quality of reviewing. Until the economic evaluation policy is fully implemented—and maybe even after—continuous capacity build-up by the government is highly encouraged and expected.

■ **Korea-U.S. trade conflict incurred by the policy.** In July 2006, when talks for the Korea-U.S. FTA began, the U.S. government demanded the cancellation of economic evaluation policy as a prerequisite for further FTA talks. Since then, the policy and its contents have become a hot subject in the bilateral negotiations. On 1 April 2007, both countries concluded the historic agreement, including provisions on pharmaceutical market access and on protecting IP rights. Details of the agreement on pharmaceuticals and patented products are to be worked out in the coming months, and it is anticipated that some of the policy contents may be reshaped. That means that the policy impact on South Korean drug pricing and reimbursement, domestic and global pharmaceutical firms, patients' access to innovation, and NHI financing is hard to assess at this moment. However, South Korean experience with the FTA makes it clear that the international political economy of the pharmaceutical market needs to be considered and prepared for in any country's health policy.

Concluding Comments

The continued growth in new health technologies offering improved health outcomes puts increasing financial pressure on health systems. Every country must find ways to ensure that resources are allocated efficiently. South Korea is no exception. The potential pressure on the Korean system may be even greater than on other systems because of South

Korea's continuous expansion of insurance coverage and loose structure of health technology management. The natural policy direction, therefore, is to devise ways to ensure that resources serve the highest priorities of the population's health needs in an efficient way. Using economic evaluation data in reimbursement decisions is the policy option that South Korea is taking.

Use of economic data could be extended to other technology areas as well—namely, medical equipment and diagnostic technology. However, how soon and how widely this policy will be extended is still undecided, since many stakeholders with strong interests in this issue, both in and outside South Korea, are watching the developments closely.

NOTES

1. Per capita income increased from US\$1,034 in 1977, when the first social health insurance program started, to US\$18,372 in 2006. Korea National Statistical Office, *Monthly Statistics*, March 2007 (Seoul: KNSO, 2007). During the 1980s, civic societies made a strong advocacy for expansion of social health insurance coverage for the self-employed. Politicians, in response to their commitments to civic groups, pushed actively to extend coverage to the self-employed, who finally acquired social protection in health in 1989.
2. Organization for Economic Cooperation and Development, *OECD Reviews of Health Care Systems—Korea* (Paris: OECD, May 2003).
3. OECD, *Statistics on Health Care Resources and Utilization*, Doc. no. DELSA/ELSA/WPI/HS (Paris: OECD, September 2004).
4. In December 2000, a reform of single prescribing and dispensing system (the Separation Policy), where physicians only prescribe and pharmacists dispense only with prescriptions, was newly imposed as a regulation. An increase in medical fees of more than 40 percent was approved by the government as compensation for loss of physician and hospital revenues that resulted from the implementation of the Separation Policy.
5. Health Insurance Review Agency, *List of Pharmaceuticals in National Health Insurance* (Seoul: HIRA, 2006).
6. It is assumed that A7 (advanced seven) countries, shown in Exhibit 3, are the earliest adopters of new drugs. All new drugs under NHI review are preapproved for production and marketing by the Korea Food and Drug Administration.
7. S.K. Kim, *Health Insurance Review Agency Workshop Report* (Seoul: HIRA, January 2006).
8. HIRA, *Guidelines for Economic Evaluation of Pharmaceuticals in Korea* (Seoul: HIRA, December 2005).
9. A. Towse and C. Pritchard, "Does NICE Have a Threshold? An External View," in *Cost-Effectiveness Thresholds: Economic and Ethical Issues*, ed. A. Towse (London: Office of Health Economics, 2002), 27–28; B. George, A. Harris, and A. Mitchell, "Cost-Effectiveness Analysis and the Consistency of Decision Making," *PharmacoEconomics* 19, no. 11 (2001): 1103–1109; E. Orlewska and P. Mierzejewski, "Project of Polish Guidelines for Conducting Pharmacoeconomic Evaluations in Comparison to International Health Economic Guidelines," *European Journal of Health Economics* 4, no. 4 (2003): 296–303; and Á. Szende et al., "Methodological Guidelines of Conducting Economic Evaluation of Healthcare Interventions in Hungary: A Hungarian Proposal for Methodology Standards," *European Journal of Health Economics* 3, no. 3 (2002): 196–202.
10. Orlewska and Mierzejewski, "Project of Polish Guidelines."