Reimbursement, Regulatory and Policy Issues
Asia-Pacific Insights for the Medical Device Industry

- Economic development in the region is creating new wealth; GDP is growing at an annual rate of 6.4% (2004-2008) and will stand at 12.4 trillion USD in 2008.
- On average, countries in the Asia-Pacific region spend 5.8% of GDP on healthcare and demand is expected to rise as overall quality of life improves.
- Asia-Pacific’s medical device market is currently 31.0 billion USD and is growing at 7.3% annually with developing medical device markets such as China and Vietnam growing at 11.0% and 9.5% per year respectively.
- About 45% of healthcare funding in the Asia-Pacific region comes from the public sector; however this is a blend of countries like Japan, which bears 85% of total spending, and countries like Thailand, which bears 25% of total spending.
- Private health insurance is currently a 10.1 billion USD industry in the Asia-Pacific region and growing at 14.8% per year as third party payers move to provide broader access to care and private sector alternatives to nationalized systems for increasingly wealthy populations.
- In an effort to improve safety, regulators across the Asia-Pacific region are moving toward harmonization with global standards for the evaluation, manufacture and post marketing surveillance of medical devices. The Philippines (2007), Singapore (2007), and Malaysia (2009) are the most recent countries to announce mandatory registration for medical devices.
- In addition to regulatory harmonization, public reimbursement authorities are also beginning to share information on pricing. While still early in development on a regional basis, Foreign Reference Pricing (FRP) is gathering momentum in South Korea and is poised to gain adoption in Japan.
- New reimbursement systems are an emerging means for public and private payers to control costs. Currently, forms of the Diagnosis Related Group (DRG) system are being implemented in Australia, Singapore, South Korea, Taiwan and Thailand.
- Governmental controls on the expansion of private healthcare funding as an attractive alternative to public programs and services is a key issue because a governmental policy of broad cost containment restricts the development of vibrant healthcare markets and the infrastructure that supports them.
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Asia-Pacific Regional Report

Asia-Pacific Healthcare Funding Overview

Healthcare funding systems in Asia can be broadly categorized into three tiers: nationalized, semi-nationalized and market driven. These distinctions are primarily a function of two factors, governmental policy on the provision of healthcare services and history of economic development. These two factors have shaped the way in which individual countries have constructed their healthcare markets, the funding schemes that support them, and the regulations to which market participants must adhere.

Nationalized
A generous national insurance program covers substantially all of the population in Australia, Japan, Singapore, South Korea and Taiwan. This category has shown proactive innovation in the form of government administrated individual medical savings accounts in Singapore as well as defensive political pressure capping increases in South Korea’s private insurance premiums, limiting any expansion in healthcare financing.

The healthcare delivery infrastructure in nationalized countries is typically well developed. As a result, these countries share many of the same concerns that European countries now have over aging populations and the long-term affordability of universal coverage at current standards of care.

Cost containment measures have become a central part of government healthcare funding strategies. These cost containment measures appear in various forms including: co-payments, access to care, FRP, DRG, regulatory requirements, global budgets, group purchasing, and disease management for chronic conditions. It is very likely that, over time, the nationalized countries will find shared healthcare funding concerns and their regulatory agencies will begin to act in closer collaboration to address them. One particular area of focus for this new regional collaboration is in foreign reference pricing for products which has been embraced by countries such as South Korea and Taiwan and is under evaluation in Japan.

Semi-nationalized
Malaysia and Thailand are best described as semi-nationalized healthcare funding systems and China’s urban areas may develop toward a semi-nationalized model. Typically there is universal coverage but not everyone is covered in the same way. The government healthcare funding system covers government officials, the military and
urban populations best. While rural populations are entitled to coverage, education levels and geographic access to care issues limit consumption. Private medical care comprises a significant and growing portion of total healthcare spending. These services are currently funded out-of-pocket by those with the resources to seek higher quality care. The penetration of private health insurance in these markets is accelerating at 14.8% to fulfill an under met need.

The defining infrastructure features of the semi-nationalized system are publicly funded primary and secondary care in rural areas and tertiary care in major urban areas. Both total capacity and throughput of the public system tend to be less than the underlying demographics imply and this constraint can be observed both in facilities and manpower. A robust private care infrastructure has developed to meet demand for high quality care on a fee-for-service basis. Market forces have shaped the development of this parallel private infrastructure and it exists from GP clinics serving foreigners in rural tourist centers to highly specialized tertiary care hospitals in major cities like Bangkok or Kuala Lumpur.

Cost containment in the public system remains a key concern for governments and the focus is on delivering affordable basic healthcare to a population impacted more by infectious diseases than by aging. The administration of government bodies in the semi-nationalized countries is less robust than in the nationalized countries and thus cost containment strategies are more basic. Access to care in the public system is the most common form of cost containment. Global budgets ensure that the public system lives within its means. A lengthy process for listing acts to retard adoption of costly medical innovations while government tender squeezes suppliers. Perhaps predictably, private health insurance schemes are set to provide a larger segment of the population with access to top quality care and modern treatments.

### Healthcare Cover (% of total population) and Patient Co-payment (% of total fee)

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<thead>
<tr>
<th>Country</th>
<th>Insurance Coverage (% of pop')</th>
<th>Co-payment (% of fee)</th>
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<tbody>
<tr>
<td>Vietnam</td>
<td>100</td>
<td>20</td>
</tr>
<tr>
<td>Thailand</td>
<td>53</td>
<td>20</td>
</tr>
<tr>
<td>India</td>
<td>15</td>
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<tr>
<td>Indonesia</td>
<td>24</td>
<td>50</td>
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<tr>
<td>Japan</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>Taiwan</td>
<td>100</td>
<td>35</td>
</tr>
<tr>
<td>South Korea</td>
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<tr>
<td>Australia</td>
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<tr>
<td>Singapore</td>
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<tr>
<td>China</td>
<td>93</td>
<td>70</td>
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<tr>
<td>Malaysia</td>
<td>21</td>
<td>80</td>
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Source: WHO and interviews.
**Market Driven**

The national insurance systems in China, Indonesia, Philippines and Vietnam leave large segments of the population without coverage. There is a heavy reliance on international aid agencies to meet the basic healthcare needs of rural populations and the urban poor. Government officials, military and economically productive urban populations do best in a system where care is delivered on a fee-for-service basis and later reimbursed by the appropriate government agency. Employers also play an important role in maintaining the health of their employees but benefits are not nearly as generous as in North America or Europe.

The public infrastructure in most market driven systems was not designed to meet the needs of the entire population and therefore is inadequate for this purpose. It is not uncommon for the average patient to travel long distances to receive secondary or tertiary care, and for patients with the economic resources to travel to centers of excellence in neighboring countries to receive specialty care. These circumstances have led to a cycle of brain drain and chronic medical manpower shortages. The trend may slow however as the emergence of a top class private care infrastructure promises a better future for those who stay at home and private health insurance develops as a significant source of healthcare funding.

Cash is the defining feature of the market driven healthcare system and it controls access to care regardless of geography or medical need. Governments encourage public hospitals to be self supporting and reimbursement agencies to be ineffective and under-funded. This set of incentives has led to a number of public sector adaptations such as cross-subsidization, provision of expedited services and medical entrepreneurship. There are many moral and ethical challenges inherent to the system as market forces are applied to limited capacity, an uneven distribution of wealth and a large degree of information asymmetry between patients and providers.

**Approach to Reimbursement / Pricing**

A nation’s healthcare funding system strongly influences its approach to reimbursement and market pricing. The nationalized countries typically have fully established regulatory bodies. Although the level of sophistication varies, regulators are capable of evaluating the cost, effectiveness and the broader impact of health technologies on their own healthcare market. Reimbursement setting and adjustment mechanisms are well defined. Reimbursement levels are typically determined by comparative product benchmarks and
anticipated utilization rates. Adjustments occur at periodic intervals and reimbursement rarely rises. In response to this, industry seeks to introduce new products and so obtain a higher reimbursement level by “upgrading” to a different category with a different benchmark price.

This cycle has been the historical relationship between industry and regulators in nationalized funding systems. However, the fundamental nature of the process is poised to change as the regulatory authorities of different countries begin to share information among themselves as an aid to determining reimbursement and pricing levels. Currently a protocol for sharing information is not well developed and the burden of supplying comparative country information if often shifted to the applicant. However, there is a strong common incentive for regulators to resolve these barriers and much closer coordination is anticipated on a worldwide basis.

Less sophisticated regulatory authorities are also charged with controlling public healthcare expenditure. Authorities that do not have the ability to receive data on actual market consumption rely on the purchasing power of the public hospital system as the key mechanism to control cost. While the tender process is widely used, it is most aggressive in Taiwan and conspicuously absent in Japan. Under a tender system, products are typically ranked by their cost and complexity with physicians making decisions on more complex products and administrators making decisions on less complex products. There are many permutations to the rules of government tenders and manufacturers have adopted strategies such as bundling and decreased sales support to regain leverage. Special departmental budgets and consignment agreements also exist in the public sector so that senior physicians can obtain non-tender products, often at market prices.

Market pricing in the private sector often helps to compensate manufacturers for purchasing squeezes in the public sector. In markets such as Australia, the price to the private market can be as much as double the price to government with innovative products typically available in the private sector two or three years before they are made available in the public sector. Throughout the region, higher value products are sold on a consignment basis. The additional cost is passed on to patients, often as a lump sum for a certain procedure. However, the increasing penetration of non-governmental health insurance will impact pricing in market driven countries. Private insurers in Australia currently use government listings to inform decisions on what products will be covered and to what extent. As the scope and scale of third party payers increases in Asia, they will become more sophisticated and capable of influencing price through negotiated reimbursement.

**Regulatory Environment and Policy Trends**

The medical device regulatory environment in Asia is moving toward global harmonization based on increasing consumption of medical technology and a desire to protect populations from unsafe and ineffective products. Comparatively developed countries in North Asia have already begun the process. ASEAN has been identified as an international body that could provide a framework for harmonization efforts in the South. Currently, the Medical Device Product Working Group of the ASEAN Consultative Committee on Standards and Quality is focused on the following policy
developments that are representative of the general direction that regional harmonization will take:

- A common submission dossier template for product approval in ASEAN,
- An abridged approval process for medical devices which regulators of benchmarked countries or recognized regulators have approved,
- A harmonized system of placement of medical devices into the ASEAN markets, based on a common product approval process,
- A post-marketing alert system for defective or unsafe medical devices,
- All ASEAN countries joining the Asian Harmonization Working Party and work in parallel with the Global Harmonization Task Force (GHTF) on technical harmonization efforts. GHTF is an international group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception in 1992, GHTF has encouraged convergence in regulatory practices. This has been achieved by publication of guidance documents on regulatory harmonization.

The Philippines, Singapore and Malaysia are the most recent countries to advance towards more regulated markets and harmonization around international standards. The switch from voluntary to mandatory registration is expected to be effective by the end of 2007 in The Philippines and Singapore and the middle of 2009 in Malaysia. However, there are some limitations on the rate of convergence. Specifically, an investment in regulatory infrastructure, adequately trained manpower, and the integrity of the core government apparatus all play a role in the rate at which nations will harmonize.

While there is no current common standard, medical devices are typically divided into three or four classes based on risk. There is a degree of difference in how each regulatory body groups specific products. In general, however, products fall into alignment with international standards where Class I represents the lowest-risk and Class III/IV represents the highest risk.

At this time, data package requirements for registration vary from country to country. GHTF Study Group 5 is developing harmonized guidance on the content and format for clinical investigation reports and on how to conduct and document a clinical evaluation. Convergence of regulatory requirements for evidence of clinical safety will have a

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<td>Mandatory registration</td>
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<td>Local clinical trials</td>
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<td>GMP audit</td>
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Note: partially shaded check marks denote requirements for high risk products that are not always applied.
significant impact on the integrity of the registration process. Under current rules, Category I products do not need to have clinical data. For Category II and Category III/IV products, clinical data is normally submitted. If the product already has obtained approval in country of origin, Europe, or America, foreign data is accepted and no local clinical trial is needed. The notable exception to this is Japan, where domestic clinical trials are often required. For local medical devices or devices without any approval, a local clinical trial is required to prove the safety and efficacy of the product.

The implementation of Good Manufacturing Practice (GMP) certification is gaining momentum in Asia. The nationalized countries such as Japan and Australia already have their own well developed GMP requirements. Developing Asian countries now look for European or American GMP certificates from foreign manufacturers of invasive medical devices as a certification of safety after tragic failures of low cost products imported from non-GMP compliant countries.

Registration fees and annual fees to supply products to Asian countries are quite low across the board at a few thousand dollars per product. However, the cost of assessing conformity to a country’s manufacturing standards and regulations can be considerable at several hundred thousand dollars. This manufacturing site validation process can require multiple site visits as well as costly test batches.

Currently, post marketing studies are generally not required in the Asia-Pacific region. Exceptions occur and are usually initiated by a stakeholder with a substantiated reason for further scrutiny. The current environment is changing as overall regulation increases. South Korea is considering implementing a mandatory PMS requirement and GHTF Study Group 2 is reviewing current adverse event reporting, post-market surveillance and other forms of vigilance with a view to harmonize data collection and reporting systems. Re-approval is standard practice although the requirements range from a complete repeat of the registration process to refilling a GMP certificate. The timeline for re-approval also varies but is usually in the range of every two to four years.

**Opportunities and Risks for Industry**

Wealth is increasing across the Asia region as the rewards of economic development trickle down through local economies. As a percent of GDP, governments and patients
will have more funds to spend on healthcare than ever before. Affluent segments of the population will drive private sector consumption of high quality care. This increase in demand poses a challenge for the supply side as both public and private healthcare providers develop new capacity and business models. Industry has a role to play as a participant in the debate on access to care and quality of care as new demographic and economic realities take hold.

However, not all of the healthcare systems in Asian nations are starting at the same point and there is a degree of uncertainty in the evolutionary process. What is more certain is that the three distinct categories of healthcare systems that currently exist in Asia (nationalized, semi-nationalized and market driven) will not follow a linear progression as the level of economic development increases. The generous national coverage provided to the citizens of Japan will not be replicated in China or India. It is very likely that Asia will witness the emergence of hybrid healthcare markets that provide different levels of care and service in the same geographic location and perhaps in the same physical infrastructure. Industry must help governments manage the social implications of the development of multi-tier healthcare markets.

Essential touch points for industry as Asian economies mature:

- Engagement on access to care and reimbursement standards including the evolution of full DRG systems in the nationalized Asian countries (all countries),
- Input to government on Foreign Reference Price (FRP) initiatives (South Korea, Taiwan and Japan),
- Harmonization of regulatory standards around well defined global criteria and a voice in the development of policy by ASEAN / GHTF (all countries)
- Focus on the measurement of product effectiveness and impact on patient quality of life with regulators and the key opinion leaders that advise them including healthcare economic tools like quality-adjusted life years (QALY) and health technology assessments (HTA) (Australia, Japan, Singapore, South Korea, Taiwan)

Source: Espicom market research; LEK analysis
• Endorsement of higher safety standards including GMP certification and adverse event reporting to exclude low quality competitors from regulated countries (Australia, China, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan),

• Stronger legal frameworks for the protection of intellectual property, compliance with World Trade Organization standards for member nations, and response to compulsory licenses for branded products in nations that are not WTO members (with special focus on Indonesia, Thailand and Vietnam),

• Advocacy for a robust private sector and a softening of the conflict related to serving the general population with affordable basic healthcare while also developing global hubs of medical tourism and biomedical innovation (Philippines, Singapore, South Korea, Thailand),

• Support for the training and education of medical manpower within the public system and access to advanced technologies and techniques (Indonesia, Malaysia, Philippines, Vietnam),

• Reduce value leakage via distribution system reform and elimination of corrupt practices (China, Indonesia, Japan, Malaysia, Philippines, Thailand)

• Visible public service investments in local communities and targeted philanthropy to ensure the neediest people are not left behind (China).

Closer communication among the reimbursement authorities of Asian countries and their counterparts in Europe and North America is a specific risk that industry must act to manage. The near term impact will be most obvious on pricing as regulators from nationalized healthcare systems reference a product’s price in their chosen basket of comparative markets. Industry must have a voice in defining what markets are truly comparable and why. The longer term impact will be around an evolution towards conformity on how products are used, treatment algorithms, sharing of evidence based medicine, mining vigilance databases, and the development of advanced healthcare economic tools. Industry must not allow government regulators to unilaterally dictate the most effective way for clinicians to use, manage and provide care in nationalized settings.

Value leakage, or the difference between the ex-manufacturer price and the retail price, is a problem in several Asia-Pacific countries and is almost always a direct result of government policy. The risk for industry lies in public sector endorsement of value leakage as a hidden tax on industry to subsidize the income of healthcare providers and/or local distributors. Endorsement is most often implicit, in the form of very low wages paid to doctors and thin global budgets paid to hospitals in countries like China, Indonesia, Philippines, Thailand and Vietnam.
Occasionally, government endorsement is explicit as with the mandatory use of Bumiputra agents in Malaysia. Entrenched local distribution networks in Australia, China, Indonesia, Japan, Philippines, South Korea and Vietnam add to leakage problems. Collective action by industry groups to link value leakage issues to global standards harmonization through directly engagement with policy makers is perhaps the best strategy to reduce the occurrence and magnitude of value leakage.

Finally, increasing sophistication of third party payers writing policies in the Asia-Pacific region is an associated risk that should also be actively managed by industry. Economic development and the emergence of a robust private care infrastructure will prompt payers to evolve their cost containment strategies. Currently, payers are beginning to apply either reimbursement caps or defined reimbursement levels for certain product-types. Industry should leverage its competency in more advanced insurance markets, such as the United States, to ensure that manufacturers and patients receive access to high quality products and that DRG or other accounting systems properly compensate providers for using these technologies.

Penetration and Growth of Private Health Insurance

Source: WHO country healthcare accounts