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# ASIAN PRICING AND REIMBURSEMENT

## *How to compete and succeed in a rapidly changing market*

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# ASIA

## *A land of pharma opportunity and financial challenges*

Growing major trends are emerging across Asian healthcare markets. Rising incomes, increased government healthcare expenditure, higher life expectancies and a surge of chronic illnesses are boosting the demand for pharmaceutical products and services in the region.

This sea of change is also being driven by multiple factors including government healthcare reforms, increasing Universal Health Coverage (UHC), the rise of private financing and heavy promotion of the generic market.

This offers a significant opportunity both for established pharmaceutical companies in the region who wish to continue to thrive and for those considering entering the Asian market. However, it also presents a unique set of regional challenges and commercial success will be dependent on understanding the complexities of the Asian pricing and reimbursement environment.

### *Opportunities within a changing Asian market*

The Asian healthcare landscape is a dynamic one. The region consists of a wide diversity of healthcare markets in very different stages of development, particularly with regard to their healthcare infrastructure.

The healthcare environment within Asia is changing dramatically and spending in the region has shown an explosive rise in recent decades. Between 2009-2012 Asian markets showed the highest growth of per-capita healthcare spending in the world, at 38.8% of CAGR compared with the global average of 26.3%.[1] The sharp increase of healthcare spending in this region can be explained by several factors, including growing economies, expansion of the middle class, the rise of chronic illness and increased life expectancy.

To meet this rapid growth, Asian healthcare systems will need to expand and adapt. As more countries implement healthcare reforms, leading to greater patient population coverage, countries across Asia will need to address pricing and reimbursement challenges to meet healthcare demands.

What drives Healthcare spending in the region?[6]


*People of age 65 and above

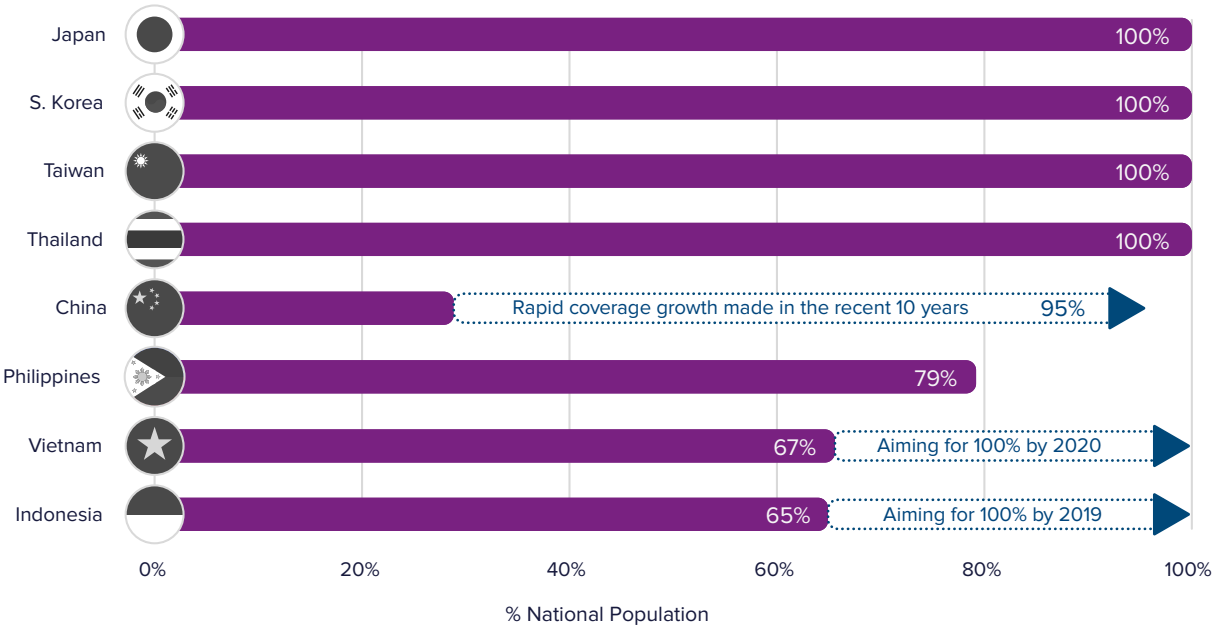
[1] World Health Organization, 2013.

# *Emerging trends across Asian healthcare systems*

## *1. Increasing Universal Health Coverage (UHC)*

Increasing UHC is a high priority for many governments across the region. Some Asian countries already offer 100% universal health coverage. This means every single citizen is eligible for at least some form of public healthcare subsidy. Other countries currently offer limited UHC, however their governments have pledged to achieve 100% coverage before the end of the decade (Figure 1).

Figure 1: Public healthcare coverage across Asia4




Increasing UHC is widely believed to drive better patient accessibility to healthcare systems in the region. However, it is also one of the most prevalent challenges in the Asian healthcare market, and the implementation and execution of UHC varies from country to country.

China is leading the trend with rapid growth of public health coverage in the last decade (Figure 1). It offers a Basic Health Insurance Scheme (BHIS) and in 2003 launched a New Rural Cooperative Medical Scheme (NCMS) which offered coverage to 98% of its rural poulation as of 2013. However, total healthcare spending in China, as a percentage of GDP, still remains very low compared to OCED (Organisation for Economic Co-operation and Development) countries and the rapid rise of patient demand is not properly addressed by the Chinese public sector.

Whilst 'thin' healthcare coverage is a common issue across many Asian countries, countries like Indonesia have a different set of challenges. Here the private market is entirely separate from the public market i.e. the former is entirely run by private healthcare providers with 100% OOP (out-of-pocket) payment, and the latter is run by public healthcare providers with 100% government subsidy.

This market formulation is different from those found in Japan and South Korea, where the private and public market are mixed and the majority of private healthcare providers still offer 70-95%-subsidised treatment options.

The main historical reason for an entirely separate market formulation is that the government does not play a leading role in controlling the healthcare market. Therefore expensive drugs are freely priced based on market dynamics, forming a 100% OOP based private market. The challenge is that the free public markets in this region do not have sufficient infrastructure to cover increasing healthcare demand in terms of treatment quality and rural accessibility. These governments are now pledging to achieve 100% healthcare coverage by the end of this decade. However, it remains in question whether they will find a solution to formulate an ideal private-public market mix which adequately addresses the increasing healthcare demand.

## 2. *Rise of private financing*

Along with an increase in healthcare coverage, the region has also seen a sharp increase in public spending on healthcare. For example, China and Thailand have increased their public healthcare spending over the last 10 years (2004-2013) at the CAGR of 6.2% and 5.4%, respectively.[2] Both of these are much higher than the 1.62% growth of average public spending of OECD member countries during the same period. However, healthcare spending per capita in the two countries has also sharply grown at an even higher rate (13.7% and 8.4%, respectively) over the same timeframe. This illustrates that increased public spending does not adequately address increasing healthcare demand. In fact, many national and regional payers in the region are in deficit, facing a shortage in their public healthcare fund.

In the developed world, increased public funds may be used to help support patients' treatment cost and better healthcare services, such as expanding the reimbursement tier to include expensive therapies. However, this is not the case for the majority of Asian developing countries. For many countries across the region, increased public funding is increasingly prioritised to establish healthcare infrastructure, which does not necessarily alleviate the direct OOP cost in the near-term. In addition, government inefficiency and corruption often makes matters worse.

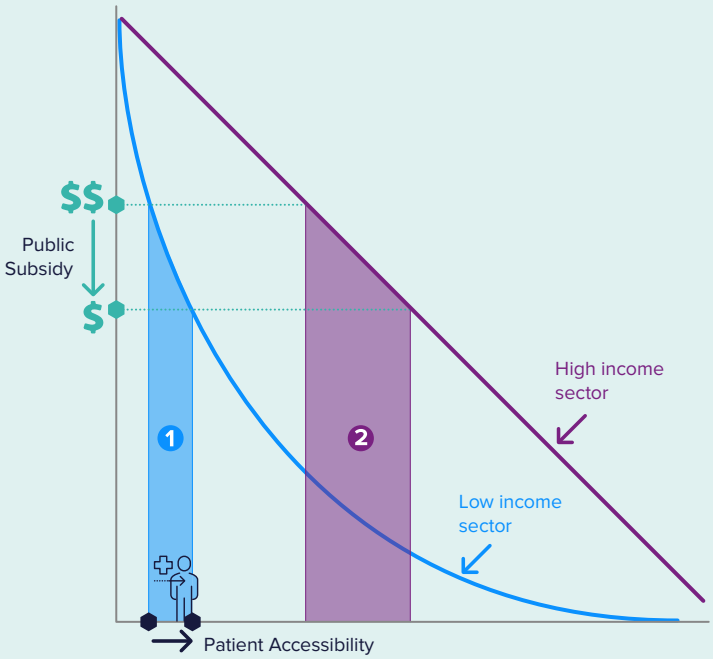
In general, the relationship of Patient accessibility to Drug price (represented as Public Subsidy in Figure 2) in the poor sector is not as In general, the relationship of Patient accessibility to Drug price (represented as Public Subsidy in Figure 2) in the poor sector is not as near-linearly proportionate as it is in the high-income sector. Many countries in the Asian region face the issue that the market gap between **1** and **2** is inadequately addressed. Governments across the region understand that improving healthcare provision cannot be supported by public resource alone. Countries are therefore increasingly promoting, or leveraging, the private financing sector to reduce the market gap.

China is now planning to provide tax benefits to promote the private financing sector to contribute towards total healthcare spending. Currently, private insurance in China only contributes to 1.3% of the total healthcare expenditure.[3] India has also recently revised the FDI (Foreign Direct Investment) cap from 26% to 49%, anticipating it will boost the private insurance sector, which currently only covers 13% of the population.

Vietnam's private insurance coverage is already very high at 74.2% (2013) with an annual growth rate of 11.1% since 2008 - this is widely attributed to the role of state-owned insurance companies. The Vietnamese government aims to achieve 100% healthcare coverage by 2020, by leveraging the high level of private insurance coverage.

South Korea is one of the countries where private insurance coverage is high despite relatively high government subsidies. This is mainly due to strictly enforced drug reimbursement guidance to clinical practice and insufficient subsidies of high in-patient costs. Approximately 64% of the population hold one or more private insurance programs, which account for 90% of the private treatment cost in the country. In Japan, private insurance is limited due to the very high level of public coverage. However, supplementary insurance programs such as dental services, group health exams and cosmetic surgery, are increasingly gaining traction, and 70% of Japan's adult population hold this type of insurance.[4]

Figure 2: Illustrative relationship of Public Subsidy vs. Patient Accessibility




At the same level of public subsidy, increased portion of accessible patients from low-income sector **1** is much lower than that from middle-to-high income sector **2**.

[2] World Bank Data, 2015. [3] Yonhap News, 13 July 2015. [4] Global Data Country Focus Reports 2013-2015.

## 3. Increased emphasis on cost-effectiveness

Pharmacoeconomic evidence becomes increasingly important in P&R decision making in Asian countries. This will lead to a higher planning burden on pharmaceutical companies with a less clear return on investment and likelihood of success.

The Health Technology Assessment (HTA) policy framework is slowly penetrating Asia. The use of HTA is quite dynamic across the region and different countries are progressing at different rates and are at varying stages of development.

Due to high healthcare expenditure, South Korea introduced a cost-containment strategy in 2006. There was a shift from a negative listing to a positive listing system (PLS) and a change in priority towards promoting clinically, as well as economically viable, drugs with the implementation of HTA. In 2011, the first revision of PLS resulted in voluntary price cuts and 60.6% of new drugs were rejected on the grounds of obscure or unacceptable cost-effectiveness. Taiwan and Thailand also introduced HTA in the late 2000's around the same time as Korea.

Japan announced in 2014, following a couple of postponements, a plan stipulating the trial rollout of cost-effectiveness assessments in 2016. Discussions have gained momentum in recent months. Previous free-pricing Asian markets are now also seeking more structured pricing mechanisms.

China's pricing system gained more structure with the introduction of external referencing and price negotiations with drug companies. In India, the DoP is contemplating the introduction of price negotiation.

The increased emphasis on cost-effectiveness in this region will drive a higher market entry hurdle.

Pharmaceutical companies will need to prepare an additional pharmacoeconomic dossier to access markets in the region. However, this also means that there will be more reimbursement market opportunities for innovative multi-national players. The Korean national payer for example, introduced Risk Sharing Schemes in 2014 as a part of the government's recent fast patient-access initiatives.

On-going HTA harmonisation initiatives across the region will ease the burden of market access planning.

## 4. Payers' buying power increasingly leveraged

The cost of pharmaceutical drugs account for a significant proportion of healthcare expenditure in Asia. Countries in the region leverage their buying power in various ways to control drug prices. This often generates a significant opportunity for the domestic pharmaceutical industry to grow.

Frequent volume-based price cuts have led to Taiwan having the lowest drug prices in the developed world and the government is now implementing even harsher measures. As of 2014, Taiwan's drug spending represented 25% of NHI's medical cost. To control drug spending, there have been frequent PVA (Price-Volume Agreements), which has resulted in low drug prices and attracted much criticism from industry stakeholders. During 2015, the NHI is trialling new drug expenditure target system that is anticipated to offer greater predictability and stability than the current PVA system.

PVA is generally more favourable to the domestic industry, which is minimally affected under the scheme. Domestic players largely focus on local innovator drugs, IMDs (incrementally modified drugs or super-generics) and non-branded generics, of which sales volume hardly triggers price adjustment. As such, the scheme is frequently leveraged by the governments to protect and nurture the domestic pharmaceutical industry across countries in the region.

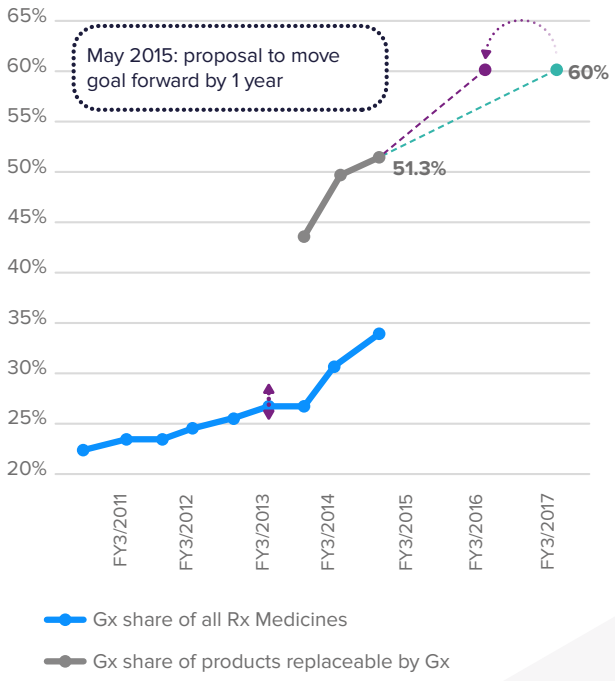
The Hospital/Provincial tenders are also being leveraged as a cost-containment tool. South Korea's MATP (Market-based actual transaction pricing) allows the National payer to regularly revise the list price based on the actual market price monitored at hospital bidding. Hospitals are incentivised to seek cheaper alternatives under the scheme, so domestic innovator drugs or IMDs often win over me-too global innovators, allowing them to gain significant traction to become the local blockbuster. The Chinese government also aims to bring in free market pricing by promoting price negotiation at hospital level as well as driving fierce provincial and hospital bidding.

## 5. *Heavily promoted generics in the region*

Japan used to be the last bastion for branded drugs, whilst generic usage was lowest among the developed countries. However, in recent years, Japan has been rapidly shifting towards a greater use of generic products wherever possible (Figure 3). Targets for generic substitution rates are accelerating and are on track to be met. The first target was set in 2007 to achieve 30% generic substitution by 2013. Since then, a 60% target deadline was set to meet by 2018. This has recently been brought forward to 2017.

Likewise, many other Asian markets are introducing pro-generic policies which significantly affect pricing and reimbursement for pharmaceutical companies. South Korea's Equal Maximum Pricing (EMP) mandates originator drug price to drop by 30% upon generic entry, with subsequent price equalization across all the generics and the originator after a certain period. The Chinese government is also keeping pressure on MNC's off-patent drugs. The government's "zero hospital mark-up policy" is aimed to prevent unnecessary prescriptions and to curtail the incentive of hospitals to prescribe off-patent drugs.

Figure 3: Comparison of generic drug share in Japan[5]




[5] Carole Bruckler, 'Is the Pharmaceutical Industry ready for increasing competition in Japan?' Deallus Consulting, CI in Pharma, Tokyo 2015.

## *What are the implications for the industry?*

**Incremental innovation** - This has high potential in the IP-protected niche Asian market, where originator drugs are under high-cost pressure. This includes super-generics (IMDs, incrementally modified drugs), biosimilars and the bio-better market. Timely market introduction of next generation drugs (new formulations, improved administration routes and dosing schedules) are very important in a country such as Korea where generic market erosion is very sharp.

**Reinvention of mature brands** - Instead of a reduced focus on mature brands within portfolio, some multinationals are reinventing mature brands by launching them at market-specific prices within targeted Asian markets. Global companies with their own generic arm often offer country-specific generic level prices in selected markets, and this strategy is sometimes leveraged to preempt Compulsory Licensure as well.

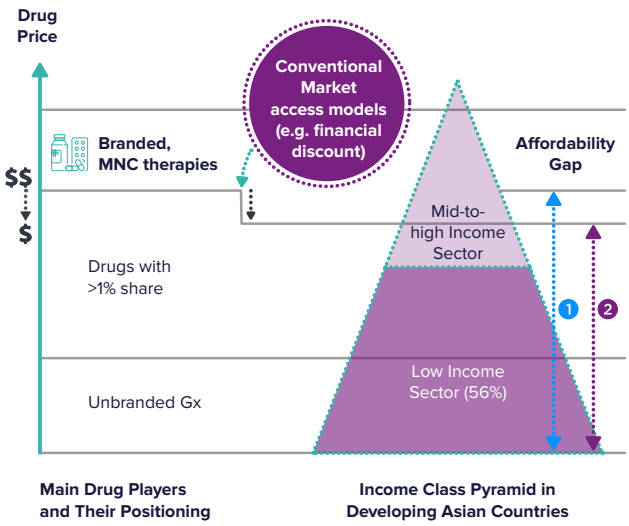
**Where to launch first?** - Where to enter first is becoming more important than ever in the region. Due to the rising emphasis on cost-effectiveness and more structured pricing schemes, increased resources are required for targeted Asian market entry planning.

**Branded generic opportunities** - There is significant opportunity for branded generics in Japan. The domestic Japanese industry needs to keep pace with the expansion of the generics industry. Small domestic companies face the dual challenge of 'Maintaining reliability of supply and of quality' and 'Accomplishing this under reducing margins due to downward pricing.' Global scale MNCs, that are already adapted to such an environment, will be able to expand and create a niche market.[5]

**Shifting business models** - Multinationals need to shift the business model to a mature market model in China. Historically multinationals have been reliant on off-patent drugs as a revenue source in the country. Along with the separation of dispensing and prescription scheduled in 2017, Chinese Government's initiatives on 'zero mark-up' policy will effectively push multinationals to focus more on new drugs as revenue sources.

**Market access innovation** - This is imperative in order for pharmaceutical companies to address the unaffordable patient sector in the region. As illustrated in Figure 4, conventional market access tools, such as financial discount offering, does not reduce the affordability gap between the middle - and low - income sector in developing Asian countries. This is because patient accessibility increases at a very slow rate as previously illustrated in Figure 2.

Figure 4: The affordability gap commonly found in developing Asian countries




Conventional market access tools do not adequately address the low-income patient sector, for which an affordability gap persists (**1** - old gap, **2** - new gap).

# *Conclusion*

The future Asian healthcare landscape is evolving and represents a significant growth opportunity for the pharmaceutical sector. Having a broad understanding of the region's pricing and reimbursement complexities will help pharmaceutical companies to compete and successfully launch new products into this dynamic changing market.

## About Deallus

Deallus is a unique strategic intelligence consultancy operating across the global life sciences sector.

Our mission is simple: to prepare you for the future by delivering the forward-thinking assurance you need in an uncertain and highly competitive world.

The knowledge and clarity we provide helps life sciences companies shape future markets by making the right strategic decisions with confidence.

## About the Author

Dr. Ju Hyoung Lim has extensive expertise within the Asian pharmaceutical market. He has an expert knowledge of pricing and reimbursement, biosimilar development and competition, and various therapeutic areas including Oncology, Autoimmune, and Infectious Diseases. Dr. Lim received his doctoral degree in microbiology from KAIST (Korea Advanced Institute of Science and Technology), and worked as a postdoctoral fellow at MIT (Massachusetts Institute of Technology) in Boston, USA. He has been with Deallus for over 5 years and currently holds the position of Senior Manager in Singapore.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