

# MakroCare Regulatory update

Asia Focus



## ASIA - PACIFIC

### EDITOR

The Pharmaceutical market world over is experiencing significant shift. Asia-Pacific region is emerging as the fastest growing pharmaceutical market. The reason for this positive shift can be attributed to the low costs and favorable regulatory environment.

Asia-Pacific region has experienced important developments regarding contract manufacturing, especially in generics and APIs. An increased R&D activity in the region has helped Asia-Pacific pharmaceutical industry to achieve an estimated market size of around US\$ 187 Billion in 2009. And it is expected to grow at a CAGR of around 12.6% during 2010-2012.

The pharmaceutical market in each country is dominated by handful of Local & Multinational companies. Pharmaceutical landscape for both Multinational Companies and Asian-based Domestic Pharmaceutical companies is radically different," "The Big Pharma business model is in transition and most of these companies are still focused on sales and marketing while they outsource other activities.

With increased changes in the regulatory landscape navigating Asian Markets is quite challenging. There are varying degrees of complexities, diversity with requirements and reporting, language issues, and predictability of timelines. Also, each country has its own set of clinical trial and market authorization requirements and processes. Safety reporting rules are not harmonized and in most of the countries the reporting requirements are still not clear.

To demystify these complexities MakroCare had initiated this online series of Newsletter. Asia-Pacific e-newsletter aims to bring highlights on recent pharmaceutical market scenario, current health care trends, regulatory changes and many more in Asia (China, India, Indonesia, Japan, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam).

***Ravi Varahalu***

## Asia at a Glance

As per the current statistics Asia accounts for more than 60 percent of the world's population and offers a large, relatively low-cost workforce in some countries and a potentially huge pharmaceutical market.

The Asian pharmaceutical sector is forecasted to grow by an estimated 9 percent to 12 percent from 2010 through 2014, compared to North America and Europe's estimated 5 percent to 8 percent

This region could be vital to the future of the global pharmaceutical market. However pharmaceutical industry faces a new array of Asia-specific opportunities and challenges. Success in addressing these challenges will go to those pharmaceutical companies that best understand the unique strengths and constraints of Asia's diverse cultures, talents and markets.

Pharmaceutical sales are growing at a fast rate in China, India, Indonesia Malaysia and South Korea due to the rising disposable income, health insurance schemes and improving healthcare infrastructure. China's pharmaceutical market is growing at an average annual rate of 16.72% over the last few decades, and will

contribute 21% of overall global growth through 2013. India - 3rd Largest Producer of Pharmaceuticals across the World- is growing at 10% in the year 2010.



The Japanese pharmaceutical market is the second largest market with sales of \$60 billion constitutes approximately 11% of the world market. However, it is a market that is annoying major pharmaceutical companies, but with growing geriatric population, constantly bloating healthcare bill it is encouraging the use of generics. This can open the flood gates of world's second largest pharmaceutical market.

Singapore government is taking strong initiatives to make Singapore a hub for biotechnology and research in the Asian region. In recent years, it has taken various steps like providing strong infrastructure and venture capital to give it an edge over other countries in Asia.

**Top 10 Pharma Destinations:**

**China**

China will see over 20% annual growth in the coming few years as the government’s healthcare reform plan will be a key driver of pharma growth in the country. The government is spending \$125 billion between 2009 and 2011 to provide 90% of its 1.3 billion people with healthcare coverage, creating a massive growth opportunity.



China’s changing demographics - the ageing population for example - also offers new opportunities for pharmaceutical companies.

**Gross Domestic Product-GDP Value in US\$:**

4909 billion dollars

**Growth:**

China is expected to reach \$40B in market size in 2013, making it the 3rd largest pharmaceutical market worldwide.

- Driving factors attracting international investment include:
  - ▶ WTO accession
  - ▶ Low labor costs
  - ▶ Tax incentives from the Chinese government
  - ▶ R&D collaboration opportunities

**Regulatory landscape:**

Application Time	Clinical Trial Application	New Drug Application	Application for Generic Drugs
Timelines required	<ul style="list-style-type: none"> <li>• CTA: 90 days</li> <li>• Special approval: 80 days</li> <li>• CTA of imported product: 160-200 working days</li> </ul>	<ul style="list-style-type: none"> <li>• NDA: 150 days</li> <li>• Special approval: 120 days</li> </ul>	<ul style="list-style-type: none"> <li>• Generic Drug Application-160 days</li> </ul>
SFDA	<a href="http://eng.sfda.gov.cn/eng/">http://eng.sfda.gov.cn/eng/</a>		

## India

The Indian pharmaceutical sector has posted double digit growth rate in the last five years and is presently accelerating at a pace twice more than the global pharmaceutical market. In near future, the potential and opportunities in this market will rise by several folds. In fact, the Indian pharmaceutical market is expected to grow at a CAGR of 14% between 2009-10 and 2014-15.



### Gross Domestic Product-GDP Value in US\$:

1296 billion dollars

### Growth:

Indian pharmaceutical market, which is currently valued at USD 20 billion, is growing at compounded annual growth rate of nearly 14% in the next few years; the Indian pharmaceutical market is expected to touch USD 40 billion by 2015. India's potential in R&D will be between US\$ 8 to 10 billion by 2020.

- Driving factors attracting international investment include:
  - ▶ WTO accession
  - ▶ Low labor costs
  - ▶ Tax incentives from the Indian government
  - ▶ R&D collaboration opportunities
  - ▶ Contract Manufacturing Opportunities
  - ▶ Highest number of US FDA approved plants outside USA

Indian business model is focusing on global scale partnerships with capable firms for future growth.

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Application for Generic Drugs
Timelines required	<ul style="list-style-type: none"> <li>• IND: 60-80 days</li> </ul>	<ul style="list-style-type: none"> <li>• NDA: 45 working days (1st response)</li> <li>• Registration: 180-270 working days</li> </ul>	<ul style="list-style-type: none"> <li>• ANDA: 180-270 days</li> </ul>
CDSCO	<a href="http://cdsco.nic.in/">http://cdsco.nic.in/</a>		

## Japan

Skills and technology available in Japan are easily comparable to Western standards. Japan is recognized worldwide for its innovation and advanced technological standards. The proportion of the healthcare budget spent on pharmaceuticals very high when compared to other developed pharmaceutical markets. Total health care expenses borne by the government is expected to rise from 6.6% of GDP in 2005 to 13.5% GDP by 2035. Hence government is targeting to increase the generic share of the market to 30% by 2012



### Gross Domestic Product-GDP Value in US\$:

5068 billion dollars

### Growth:

Japan comprises of strong patented drugs market & promises to be one of the most lucrative generic markets in the world.

- Driving factors attracting international investment include:
  - ▶ Encouraging moves on the generic side
  - ▶ Regulatory relaxation on manufacturing and clinical trials

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Application for Generic Drugs
Timelines required	• IND: 30 days	• NDA: 24 Months	• Generic Drug:12 Months
PMDA	<a href="http://www.pmda.go.jp/english/index.html">http://www.pmda.go.jp/english/index.html</a>		

## Singapore

Singapore has emerged as a key partner for leading pharmaceutical and biotech companies that seek to accelerate drug discovery in Asia. Singapore has successfully transformed into a major biomedical manufacturing hub and established its position in Asia.



### Gross Domestic Product-GDP Value in US\$:

182 billion dollars

**Growth:**

Singapore has agreed to a greater market access for generics by fast-tracking the registration of drugs that have already got regulatory approval in the US, Canada, the EU, or Australia. Over the 10-year forecast period, the market will retain most of its dynamics, growing at a CAGR of 3.33%.

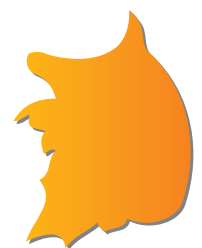
- Driving factors attracting international investment include:
  - ▶ Encouraging moves on the generic side
  - ▶ A key trading hub to connect South East Asia and the Western world and is a major re-exporter of pharmaceuticals
  - ▶ Consolidation of guidelines on pharmaceuticals, medical devices, traditional medicines and health supplements

**Regulatory landscape:**

Application Time	Clinical Trial Application	New Drug Application (NDA)	Generic Drug Application (GDA)
Timelines required	<ul style="list-style-type: none"> <li>• Clinical Trial Certificate (CTC): 30 days</li> </ul>	<ul style="list-style-type: none"> <li>• NDA: 270 working days</li> <li>• Verification evaluation: 60 working days</li> </ul>	<ul style="list-style-type: none"> <li>• GDA: 240 working days</li> </ul>
HSA	<a href="http://www.hsa.gov.sg/publish/hsaportal/en/home.html">http://www.hsa.gov.sg/publish/hsaportal/en/home.html</a>		

**Korea**

Korea has moved from being a developing pharmaceutical market to a full-fledged developed market in the past ten years. OTC medicines have been a growing segment in Korea due to the regional trend of self-prescription. Korean pharmaceutical market is yet to reach a level of growth like that of the high growth emerging markets, a scenario that may change considering the ongoing reform of pricing system for prescription pharmaceuticals.



**Gross Domestic Product-GDP Value in US\$:**

929 billion dollars

**Growth:**

Five-year compound annual growth rate (CAGR), calculated at 6.17% in local currency terms (10.35% in US dollars), will slow down to 4.98% and 7.02%, respectively, over the longer, 2009-2019 period.

- Driving factors attracting international investment include:
  - ▶ Incentives from Ministry for Health, Welfare and Family Affairs (MIHWAF) to those that in research and development (R&D)
  - ▶ Can be included as a strategic location for global trials

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Generic Drug Application
Timelines required	<ul style="list-style-type: none"> <li>• IND: 30 working days</li> </ul>	<ul style="list-style-type: none"> <li>• NDA: 145 days</li> </ul>	<ul style="list-style-type: none"> <li>• Generic Drug: 100 working days</li> </ul>
KFDA	<a href="http://eng.kfda.go.kr/index.php">http://eng.kfda.go.kr/index.php</a>		

## Taiwan

Taiwan is one of the richest countries in the Asia Pacific region. It has a strong healthcare system and the universal health insurance. The Taiwanese pharmaceutical market continues to be one of the most developed in Asia and offers good prospects for overseas investment. Taiwan is ahead of many of its Asian counterparts as some of the local players have made huge investments in building state of the art drug delivery technologies.



### Gross Domestic Product-GDP Value in US\$:

378.97 billion dollars

### Growth:

Compound annual growth rate (CAGR) of 3.72% is predicted in local currency terms, till 2014 to give the overall market value as TWD 148.1bn (US\$4.94bn).

- Driving factors attracting international investment include:
  - ▶ BOPA is considering faster approval and thereby facilitate for a speedy introduction of new pharmaceuticals.
  - ▶ If a product is approved by Bureau of National Health Insurance (BNHI), it is automatically added to the reimbursement list which allows for the prescribing of the new drug at any healthcare facility in Taiwan.

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Generic Drug Application
Timelines required	<ul style="list-style-type: none"> <li>• IND: CDE sends recommendations to DOH in 20 calendar days In total: 40 days</li> </ul>	<ul style="list-style-type: none"> <li>• NDA: CDE sends recommendations to DOH in 100 calendar days In total: 230 days</li> </ul>	<ul style="list-style-type: none"> <li>• Generic Drug: 9-12 months</li> </ul>
DOH	<a href="http://www.doh.gov.tw/EN2006/index_EN.aspx">http://www.doh.gov.tw/EN2006/index_EN.aspx</a>		

## Malaysia

The Malaysian pharmaceutical industry is an attractive sector in the Asia-Pacific region. The government has shown interest in fostering drug production, particularly in the field of biotechnology and manufacture of off-patent drugs.



### Gross Domestic Product-GDP Value in US\$:

192 billion dollars

### Growth:

Forecast represents CAGR of 10.34% over 2009-2014, increasing to 10.87% over 2009-2019.

- Driving factors attracting international investment include:
  - ▶ Government initiative like tax exemption for biotech companies
  - ▶ Conducive regulatory environment
  - ▶ Grants and financing schemes have been offered to support R&D initiatives

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Generic Drug Application
Timelines required	<ul style="list-style-type: none"> <li>• CTX: 4-8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• NCE approval: 2 years Review: 38 to 66 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• Generic Drug: 9-12 months</li> </ul>
MoH	<a href="http://www.pharmacy.gov.my/">http://www.pharmacy.gov.my/</a>		

## Thailand

Thailand scores well for Pharmaceutical market, however country structure and market risks are to be considered. Thailand will not have an immediate impact on pharmaceutical sales or the revenue earning opportunities of drug makers because the demand for healthcare is relatively independent of the trends in the economy.



The demand for prescription and patented drugs will remain assured by the fact that hospitals and physicians remain the primary access to healthcare.

### Gross Domestic Product-GDP Value in US\$:

264 billion dollars

### Growth:

Generic medicines hold a market share of about 50% in value terms and more than 80% by volume, with the coming five years witnessing further development of the sector. By 2014 Thailand's pharmaceutical market is expected to be worth THB207.60bn (US\$6.81bn).

- Driving factors attracting international investment include:
  - ▶ Government-backed BIOTECH organizations have formed partnerships with Greater Pharma and i+MED.
  - ▶ The government taking certain initiatives to increase the market's investment in research and development (R&D) activities, etc.
  - ▶ Healthcare demand constantly increasing and so larger scope for importers.

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Generic Drug Application
Timelines required	<ul style="list-style-type: none"> <li>• Clinical Application: 40 days</li> </ul>	<ul style="list-style-type: none"> <li>• NDA : Standard Review: 210 - 280 working days Accelerated or Priority Review: 100 - 130 working days</li> </ul>	<ul style="list-style-type: none"> <li>• Standard Review: 110 working days Accelerated or Priority Review: 70 working days</li> </ul>
MoPH	<a href="http://www.fda.moph.go.th/eng/index.stm">http://www.fda.moph.go.th/eng/index.stm</a>		

## Indonesia

Healthcare and pharmaceutical sector in Indonesia is considered to be more consumers driven, industry factors such annual growth of its pharmaceutical market, coupled with rising population numbers and a relatively solid political and economic base are expected to encourage multinationals to invest in the country despite a risky operating environment.



### Gross Domestic Product-GDP Value in US\$:

540 billion dollars

### Growth:

The demand for generic medicine will continue to increase because of the weak purchasing power of the people. Representing compounded annual growth rates (CAGRs) in local currency terms of 10.89% and 10.35% for 2009-14 and 2014-19 respectively. The balance of pharmaceutical trade remains negative, and is likely to grow throughout the forecast period. Sales of pharmaceutical products will increase over the next 10 years, with sales of prescription drugs and over-the-counter (OTC) medicines expected to grow from US\$2.92bn to US\$10.13bn.

- Driving factors attracting international investment include:
  - ▶ Indonesia has become an attractive base for many multinational producers to operate is largely because of the cost-effective labor force and generally low production cost

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Generic Drug Application
Timelines required	<ul style="list-style-type: none"> <li>• Clinical Application: 5 - 6 Weeks</li> </ul>	<ul style="list-style-type: none"> <li>• NCE approval: 12 - 18 months</li> <li>Review: Track I at 100 days, Track II at 150 days, and Track III at 300 days</li> </ul>	<ul style="list-style-type: none"> <li>• 9 - 12 months</li> </ul>
NADFC	<a href="http://www.pom.go.id/e_default.asp">http://www.pom.go.id/e_default.asp</a>		

## Philippines

Philippines is the most attractive pharmaceutical market among 15 major countries in the Asia Pacific region. The Philippines' pharmaceutical rating was raised as a result of the expected improvement of its domestic consumption fundamentals and the steady annual growth rate of its pharmaceutical market values.



### Gross Domestic Product-GDP Value in US\$:

160.99 billion dollars

### Growth:

Generic drugs will be the main beneficiaries, as their value to 2014 is expected to increase by an impressive CAGR of 21.64% in local currency terms. Having gained widespread popularity among consumers, generics will continue to be stimulated by the government's legislation as well as deficiencies in the country's intellectual property (IP) environment.

- Driving factors attracting international investment include:
  - ▶ The market is maturing, and there are calls to expand the socialized healthcare system to serve the entire nation, which would boost volume consumption in particular.
  - ▶ Drug companies attributed the increase to continued demand for over-the-counter (OTC) and prescription drugs for the maintenance and treatment of diseases with high incidence in the Philippines, including hypertension.
  - ▶ Healthcare affordability because of low costs.

### Regulatory landscape:

Application Time	Clinical Trial Application	New Drug Application	Generic Drug Application
Timelines required	• IND: 45 days	• NCE approval: 12 - 18 months	• 9 - 12 months
NPCB, MoH	<a href="http://www.pom.go.id/e_default.asp">http://www.pom.go.id/e_default.asp</a>		

Regulatory landscape is evolving in most of the countries they are constantly deregulating and reregulating to assist patients for the speedy access of Medicines. Through this online series of e newsletter MakroCare will update pharmaceutical Industry on the latest developments in these countries. Next addition will deep dive on the Socio-Political trends in each and every country, explore the regulatory challenges and will make an attempt to address those challenges.

Please send all your questions, queries and comments (including critical comments) to [consulting@makrocare.com](mailto:consulting@makrocare.com)