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Growth in South East Asia to exceed 11% over 5 years

DR SANJAY AGARWAL

SOUTH East Asia's pharmaceutical markets are changing due to aging populations and increasing healthcare spending.

Pharmaceuticals, as well as other industries, benefit from increased spending. New complications and difficulties have increased competition in the manufacturing of pharmaceuticals in the region adds to the mix. Fostering a dynamic climate in which industry participants can thrive is necessary to adjust. Two significant obstacles are accessing high-quality ingredient imports and expanding exports to new markets. Also, guarding against regional pharma imports, India and China are two superpowers. However, with gentrification in full swing, Singapore has a strong innovation foundation and the capacity to grow.

There are significant prospects in a new single market. The annual growth of the South East Asian pharmaceutical market is predicted to exceed 11% over the next five years, along with an expected sale of \$50 billion by 2021. Such performance makes it one of the fastest-growing pharmaceutical markets in the world. It represents the rich pickings for the pharma manufacturers who will effectively synergise the good manufacturing practices standard, export strategy, and competitive prices.

With an annual growth rate of 9.1% between the year 2016 and 2021 in the Asian markets, the pharmaceutical companies in South East Asia are still ongoing with the high growth rate in the region, which is considered the highest. The increased dependence on out-of-pocket expenses in South Asia results in low adoption of highly-priced treatments compared to the reasonably well-financed reimbursed market. The middle class is rising, yet,

many treatments are not affordable for many patients in South East Asia.

Meanwhile, governments in several South East Asian countries are grappling with a problem: keeping rising healthcare costs in check. As a result, there is price pressure on pharma companies in Asia, and they must prioritise needs, channels, and products. Commercial outsourcing to firms has shown to help businesses expand their market or channel coverage and increase product sales.

All About Manufacturing in the Region

The ASEAN economies have a strong generic manufacturing capability, which accounts for a significant portion of the region's pharmaceutical sales. However, only a few businesses in South East Asia can produce active pharmaceutical components (APIs). Imported ingredients are heavily relied upon. Only 5% of the 142 domestic pharmaceutical factories licensed with GMP standards are capable of producing APIs, according to information from Thailand's Food and Drug Administration (FDA Thailand). While reliance on imported APIs isn't unique to South East Asian markets, it does expose the market to price swings and availability from Chinese and Indian vendors.

Both Indonesia and Malaysia have comparable situations, with finalised generics dominating and imported APIs supporting them. Over 90% of pharma ingredients in Vietnam are imported, with China accounting for half of these. Prices of various raw commodities have risen in recent years, in part to currency swings. However, price increases have been driven by supply shortages as a result of manufacturing closures as China tightens environmental rules.

This puts pressure on profit margins, espe-

cially when price regulations across the region prohibit higher costs from being passed on to patients. As a result, more regional and international sales strategies are being developed. Finally, the standards are becoming widespread with the best short-term potential to support the generics-led export growth strategies.



Focus on Growth & Breakdown by the Country

Governments are starting to recognise the importance of innovation in essential sectors to keep their economies growing. Regulatory alignment in some parts of South East Asia continues to limit worldwide export possibilities despite recent advances. With tier 1-2 generics required to be manufactured to EU-GMP or PIC/S-GMP standards, this impacts export possibilities and sales access to domestic hospitals. According to estimates, hospitals accounted for 75% of Vietnam's pharmaceutical industry income in 2019, or \$4.9 billion out of a total of \$6.5 billion.

Several ASEAN countries have joined the Pharmaceutical Inspection Co-operation Scheme, which attempts to harmonise inspection procedures worldwide by creating uniform GMP standards, offering inspector training, and promoting collaboration between regional and international organisations. In addition to Singapore, Malaysia and Indonesia joined the programme in 2002 and 2012, respectively, while Thailand joined in 2016, and the Philippines & Vietnam have both expressed interest in completing the application process.

As a result, many generics manufacturers should expect more extraordinary expenses as their facilities are renovated to meet the new criteria. Still, there will be an advantage in the form of fewer duplicate GMP inspections. Despite the availability of cheaper competitors from India and China, many countries are already reaping the benefits, with Thai products gaining appeal in Cambodia, Laos, Myanmar, and Vietnam. The perception of higher quality strongly drives this.

Indonesia

The pharma industry in this country is expected to increase the revenue per capita, driving sales to the next level. Currently, 70% of medicine makers in Indonesia are domestic. Still, this percentage is likely to decline in the coming years due to \$20 billion in foreign investment over the next five years.

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Implementing an European styled serialisation

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The Philippines

The Philippines' healthcare demand is quickly rising for many of the same reasons in most other South East Asian countries. Consumer spending on pharmaceuticals will increase as the population ages and the frequency of lifestyle-related disorders rises while GDP per capita increases. It is predicted that the Philippine pharmaceutical market will grow at a rate of 4.5 per cent per year over the next few years, placing it third in ASEAN behind Indonesia and Thailand. The Philippines also has a solid manufacturing base, with 14 of the world's top 20 pharmaceutical corporations having manufacturing operations there.

Malaysia

The Malaysian Pharmaceutical Association has several concerns about the drug pricing strategy, including the possibility that patients' access to the most up-to-date medicines will be jeopardised if international manufacturers withdraw their products from the market due to unfavourable business conditions. Foreign and domestic pharmaceutical businesses will have to rethink their business strategies to keep their profit margins if these drug price limitations are implemented.

Singapore

It has a well-developed, mature pharmaceutical business, owing to the country's high per-

The Malaysian Pharmaceutical Association has several concerns about the drug pricing strategy

sonal income and reputation for high-quality, even innovative manufacturing services. The government has bolstered development with a slew of programmes to incentivise innovation. In recent years, big pharma has made significant investments in the industry, including CSK's \$130 million continuous production facility, WuXi Biologics' \$80 million biologics factory, and Novartis' \$500 million biologics plant. Singapore's biomedical manufacturing output climbed by about 10% in the first half of 2019. This has helped to solidify its image as a thriving biomedical manufacturing centre.

Conclusion

Implementing an European-style serialisation system to fight the central area of potential issues for regional and international corporations is key to South East Asia becoming a global powerhouse for pharmaceuticals. Counterfeit products are a source of concern, and our regional and international respondents were practically unanimous in their responses.

Indonesia has been the first to move forward with its serialisation plan, projected to be implemented between 2020 and 2025, while Singapore is experimenting with GS1 2D barcodes. Still, we expect more to follow suit shortly. To achieve complete harmonisation, much more effort remains to be made. The Marketing Authorisation process varies widely from region to region, as does the interpretation of national GMP regulations.

However, there is no doubt that regional exports – notable generics – are becoming more viable. International pharma is trying to expand its presence in the region swiftly, through either collaborations or direct investment. It is expected to proliferate in the short and medium term.

(The author is a leading pharmaceutical consultant)



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