Pharma revenues are expected to grow by 11% in Southeast Asia over the next five years

Southeast Asia on the cusp of a new dynamic for pharma: CPhI

The trade show host's latest report breaks down the pharmaceutical industry's transformation in Asia

Many factors are transforming pharmaceutical markets in Southeast Asia (SEA)—ageing populations, growing healthcare expenditures, wider competition in manufacturing, as well as challenges in importing high quality ingredients and pushing exports forward to new markets whilst combating imports from regional pharmaceutical giants, India and China.

CPhI's ASEAN Pharma Report: Opportunities & Threats 2020 and Beyond breaks down the findings of in-depth surveys carried out amongst pharmaceutical executives.

"To emphasise the size of the opportunity, within the next decade over half of the world's middle class will live within a six-hour flight of Bangkok," the report said. "In addition, free trade agreements with Australia and New Zealand have further opened up the region's potential," it added.

The annual revenue growth in the SEA pharmaceutical market is forecast to exceed 11% over the next five years, with expected sales of $40b in 2020. The region presents potential for manufacturers that can effectively synergize good manufacturing practices (GMP) standards, competitive pricing, as well as an export strategy.

A glimpse of ASEAN pharmaceutical manufacturing

The ASEAN economies have a reputable generics production capacity, and accounts for a large percentage of the region's pharmaceutical revenues. However, only a small percentage of manufacturers in SEA can manufacture active pharmaceutical ingredients (API) since there's a heavy reliance on imported ingredients.

According to figures from Thailand's Food and Drug Administration (FDA Thailand), of the 142 domestic pharmaceutical manufacturers accredited with GMP standards, only 5% are capable of producing APIs.

Free trade agreements with Australia and New Zealand have opened up the region's potential

Whilst reliance on imported APIs is not unique to SEA markets, it does leave the market exposed to price fluctuations and accessibility from Chinese and Indian manufacturers. Similarly, in Indonesia and Malaysia, finished production of generics dominates, supported by the imported APIs.

More intensive focus on R&D

'Thailand 4.0' is an initiative launched by the Thai government to shift the country from being a 'manufacturing hub' to an 'innovation hub.' Whilst not solely focused on pharmaceutical manufacturing, this initiative has already seen state-of-the-art facilities set up at the Thailand Science Park. The anti-malaria drug P218 has been codeveloped by Thailand's BIOTEC research centre, an early benchmark

success for what may become a larger part of the country's pharmaceutical industry makeup.

However, regulatory alignment is still holding back international export potential in some parts of SEA. Nonetheless, several countries in the ASEAN region are now members of the Pharmaceutical Inspection Cooperation Scheme, which aims to harmonise inspection procedures across the globe by developing common GMP standards, providing training opportunities to inspectors, and facilitating cooperation between both regional and international organisations. Singapore, Malaysia, and Indonesia joined the scheme in 2002 and 2012, respectively, whilst Thailand joined in 2016, and Philippines and Vietnam have both shown good interest in completing the process of applying. Consequently, many generics manufacturers can expect to see increased costs as facilities are upgraded to meet the higher standards, but it will eventually lead to an upside of reduced duplicate GMP inspections.

Indonesia

The country's pharmaceutical industry is expected to see increased revenues, thanks to the introduction of the 'Jaminan Kesehatan Nasional' (JKN), a new universal healthcare scheme. Predicted increases in income per capita will also push sales of over-the-counter medicines in the following years.

But, what is significant for overseas companies is the government's act of loosening ownership restrictions on domestic firms. Foreign investors are now able to own 100% of partnerships, up from 75%. Currently, 70% of drug manufacturers in Indonesia are domestic, but this figure is expected to decrease due to foreign investments of circa $20b over the next five years.

Philippines

The demand for healthcare in the Philippines is rapidly increasing for many of the same reasons as most other SEA countries. An aging population and higher incidence of lifestyle-related diseases, along with a rising GDP per capita, will see increased consumer spending on pharmaceuticals. The Philippine market will see a 4.5% annual growth over the next few years, according to IMS Health.

The country's generics market is forecast to grow at an accelerating rate, thanks to a number of government reforms and the pending introduction of a Universal Health Coverage scheme that will see a basic level of healthcare available for all Filipinos in the future.

The country is also well set with its manufacturing base, with 14 of the world's top 20 pharmaceutical companies owning manufacturing facilities in Philippines.

Malaysia

The Malaysian Cabinet announced in May 2019 that external reference pricing will be implemented to benchmark drug prices at wholesale and retail levels, aiming to reduce costs for consumers. These price controls will cap trade margins for drugs in the country, which will have an effect on all players in the Malaysian pharmaceutical supply chain. The Pharmaceutical Association of Malaysia has concerns with the drug pricing strategy, notably that patient access to the newest medicines may be put at risk as international manufacturers may possibly withdraw their products from the market due to unfavourable business conditions.

Singapore

In contrast with the majority of ASEAN countries, Singapore has a well-developed, mature pharmaceutical market, with a reputation for high-quality and innovative manufacturing services. The government has further supported development with a number of schemes to drive innovation. Most recently, it committed to investing $2.4b to improve manufacturing and engineering in pharmaceutics as part of a 2020 'Research, Innovation and Enterprise' plan.

Singapore's biomedical manufacturing output has increased subsequently by nearly 10% in the first half of 2019 compared to the corresponding half of 2018. This has further established its reputation as a prosperous biomedical manufacturing hub.

Generics manufacturers can expect increased costs as facilities are upgraded to meet higher standards

Promising growth areas

Biologics and biosimilars (except Singapore) are not currently seen as promising growth areas by the majority of respondents. Regional companies stated that the fastest growing segments are generics (47%) and patented small molecule drugs (33%), followed by biosimilars (13%) and novel biologics (7%). International respondents largely followed this analysis identifying the market's major potential in generics (50%) and patented small molecules (25%), with biologics (15%) and biosimilars (10%) some way behind. With pro-generic policies and cost-containment initiatives in place, demand for solid dose formulations and newer emerging export markets for cheaper and branded generics offer the fastest returns.

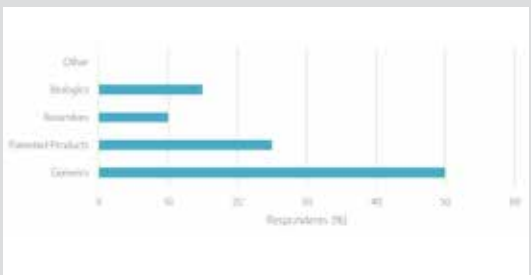
Moreover, 20% of respondents stated they sourced from the United States and 5% from Japan.

Only 27% of companies looked into currently access ingredients domestically, indicating that local economies are struggling to compete with the lower cost of the large regional manufacturers.

PIC/S offering new opportunities?

Two-thirds of respondents in the research stated that they now have greater confidence in Thai manufacturing after it joined PIC/S in 2016. However, whilst manufacturers are adapting to meet standards, there may be resultant market consolidation as smaller

Product classes with best growth opportunities in SEA



Source: CPhI South East Asia

manufacturers are struggling to compete with larger manufacturesrs due to higher costs.

Enhanced reputation and higher standards mean 47% of respondents believe that small manufacturers have now become more globally competitive and ready to export. As a consequence, a third of respondents also believe consolidation amongst smaller manufacturers is likely to occur in the near to medium term. However, 47% believe that tighter regulations and cost restraints are already leading to lower profit margins. Moreover, 80% of respondents believe the desire to control drug prices and to increase the availability of low-cost generic medicines by governments in the region will lead to increased investment in domestic manufacturing capabilities in the next five years.

Those able to achieve PIC/S standards will be able to sell more widely than they have been able to in the past. Whilst they can sell within the immediate economies regionally, achieving PIC/S standards also opens up the possibility of selling into Western markets.

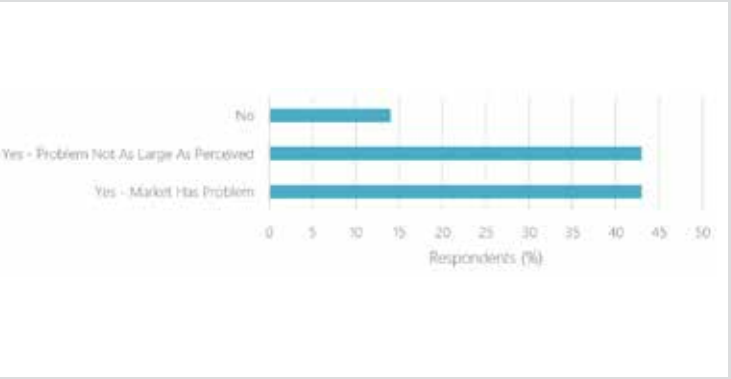
This is reflected in respondents' belief that growth in the sales of SEA-manufactured generics will come from either international sales (36%) or a combination of international and domestic sales (50%).

SEA's newest pharmaceutical hub

With the Thai government looking to make Thailand a leading pharmaceutical destination in the region, the Thailand 4.0 initiative is being rolled out—a sector-specific policy seeking to transform the Thai economy. According to an IQVIA report, the Thai pharmaceutical market is forecast to grow at a compound annual growth rate (CAGR) of 3.7% between 2017 and 2022, reaching $6m by 2022.

One change expected to accelerate the internationalisation of Thai pharmaceutics is the removal of mandatory purchasing of generics through the Government Pharmaceutical Organization (GPO). This has been met by an ambivalent response from regional manufacturers, with 53% stating that the removal of GPO requirements has either helped the market become 'more competitive,' or has 'set the price of goods.' However, 47% believe this will have an adverse effect on domestic manufacturers.

The Thai government is looking to make Thailand a leading pharmaceutical destination in Southeast Asia



Source: CPhI South East Asia

The initiative is also looking into transforming the pharmaceutical industry into one driven by innovation. Many biomedical and pharmaceutical innovation centres in Thailand have already been established. Looking ahead, the Eastern Economic Corridor of Innovation is an ambitious $45b project launched by the government to support investment in the country, a primary objective of which is to help bolster R&D through state-of-the-art translational research facilities.

One major red flag when potentially investing in the SEA region is a discrepancy in regulations and standards across the region's countries. More than half of respondents believe that standardised regulations and harmonisation across all SEA countries would make the region more attractive for investment, with a further 30% citing that they have 'agreed but that standardisation is already underway.'

Additionally, one of the risk factors identified by domestic respondents is an overdependence on foreign APIs, whilst international respondents seem largely unfazed by this.

Half believe this is the same situation for many international companies, and a further 20% cited the situation is changing—governments in the region encourage domestic or regional sources to prepare against supply chain risk from China and India.

Conclusion

CPhI's findings suggest that SEA is improving quickly, and it may be on the cusp of a new dynamic for the pharmaceutical sector.

"The headwinds Southeast Asian markets have faced in the last few years appear to be easing at the same time as tailwinds accelerate," the report said. "Significantly, the region's international reputation is improving quickly, and increased opportunities are opening up for bilateral trade," the report notes.

Generics and regional export opportunities look set for the best near-term CAGRs with international companies now more likely to partner with local assets. One of the report's most significant findings, which could potentially lead to SEA becoming a global hub for pharmaceuticals, is the creation of European-style serialisation system to combat the prevalence of counterfeit products, the biggest area of potential concern for both regional and international companies.

Indonesia has been amongst the first to move with its serialisation scheme, expected to be rolled out between 2020 and 2025, and Singapore is exploring GS1 2D barcodes, but more are expected to follow quickly in the near future.