

ASEAN Pharma Report: opportunities & threats 2020 and beyond

CPhI Southeast Asia Report (4-6 March 2020)

Overview

Aging populations are transforming pharmaceutical markets in Southeast Asia. Growing healthcare expenditures bring opportunities for pharma, but change also brings new complexities and challenges. Wider competition in pharma manufacturing across the region adds to the mix creating a dynamic environment to which industry players must adapt.

Notable challenges include accessing imports of high-quality ingredients and growing exports to new markets while defending against imports from regional pharma giants India and China. But, with gentrification underway, a strong innovation base in Singapore and the potential of a new single market, sizable opportunities are also present.

To emphasize 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 – and free trade agreements with Australia and New Zealand have further opened up the region's potential.

Annual revenue growth in the Southeast Asian pharmaceutical market is predicted to exceed 11% over the next 5 years with expected sales of \$40bn in 2020ⁱ. Such performance makes it one of the fastest growing in the world. The region presents rich pickings for pharma manufacturers that can effectively synergize GMP standards, competitive pricing and an export strategy.

Demographic Environment

Thailand's expenditure on welfare for older people is projected by Krungsri Research to rise to THB464bn (circa \$15bn) in 2021, up from just THB261bn (circa \$8.5bn) in 2016ⁱⁱ. There is strong correlation with the number of Thais in older demographic groups. The World Health Organization (WHO) estimate that 14% of the population – 10.3 million people – are now over 60. And, the situation is accelerating quickly. Thailand has one of the world's fastest aging societies. By 2025, 25% of the population

will be defined as "elderly"ⁱⁱⁱ. Indonesian and Malaysian demographics are following a similar trend.

Whilst Southeast Asian healthcare spends, per person, are increasingly in line with economic growth, these are mitigated by increasing overall health burdens. This means generics and pricing structures will continue to dominate consumption.

Manufacturing in the Region

The ASEAN economies have a reputable generics production capacity, and it accounts for a large percentage of the region's pharma revenues. However, only an extremely small percentage of manufacturers throughout Southeast Asia possess the capabilities to manufacture APIs. There is 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^{iv}. While reliance on imported APIs is certainly not unique to Southeast Asian markets, it does leave the market exposed to price fluctuations and accessibility from manufacturers in China and India.

The situation is very similar in both Indonesia and Malaysia where finished production of generics dominates, supported by imported APIs. In Vietnam, over 90% of pharma ingredients are imported. Half of these are from China^{iv}. In the last few years, prices of these raw materials have increased, in part, due to currency fluctuations. But, more significantly, there have been price rises caused by supply shortages resulting from factory closures as China tightens environmental standards. This is putting pressure on margins; in particular, as price controls across the region prevent increased costs being passed onto patients. As a result, increasingly regional and international sale approaches are being sort out. This is especially the case

among the few manufacturers that have achieved PIC/S standards. Of the major regional economies, Indonesia and Thailand – with introduction of GMP standards becoming

wider spread – appear to have the best short-term potential to support generics-led export growth strategies.

Growing Focus on R&D

Governments are beginning to recognise the need for innovation across key sectors to sustain their countries' economic growth. 'Thailand 4.0' is an initiative launched by the Thai Government to shift the country from what is described as a 'manufacturing hub' to an 'innovation hub'. While not solely focused on pharma manufacturing, this initiative has already seen state-of-the-art facilities set up at the Thailand Science Park with clean rooms, sensitive labs and high-performance technologies. In fact, already the novel anti-malaria drug P218 has been co-developed by Thailand's BIOTEC research centre, providing an early benchmark success for what may shortly become a much larger part of the country's pharma industry make-up.

Yet, despite major recent progress, regulatory alignment is still holding back international export potential in some parts of Southeast Asia. Countries in Europe and North America require facilities accredited with either EU-GMP standards or standards of the Pharmaceutical Inspection Co-operation Scheme (PIC/S-GMP). In the case of Vietnam, only 17 facilities have obtained EU-GMP or PIC/S-GMP standards, compared to 222 facilities with the lower-level WHO-GMP standards. Alongside the effect on export potential, this also prevents sales access to domestic hospitals; with tier 1-2 generics required to be manufactured to EU-GMP or PIC/S-GMP standards. Estimates suggest that hospitals accounted for 75% of Vietnam's pharmaceutical industry revenue in 2019, equating to around \$4.9bn of the \$6.5bn total.

The number of EU-GMP and PIC/S-GMP facilities in Vietnam is a serious problem curtailing the two key growth pathways noted above. It is here that ready investment opportunities for foreign companies present themselves as domestic companies look for partners to help transform production technology. A recent example includes Germany's STADA who invested a 72% indirect shareholding in Vietnam's Pymepharmco^v, which owns one of the 17 accredited facilities.

However, several countries in the ASEAN region are now members of the Pharmaceutical Inspection Co-operation Scheme, which aims to harmonise inspection procedures across the globe by developing common GMP standards, providing training opportunities to inspectors, and facilitating co-operation between both regional and international organisations. In addition to 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^{vi}. Consequently, many generics manufacturers can expect to see increasing costs as facilities are upgraded to meet the higher standards, but it will of course lead to an upside of reduced duplicate GMP inspections. The rewards are already being reaped in many markets, with Thai exports growing in popularity amongst immediate neighbours, Cambodia, Laos, Myanmar and Vietnam – in spite of cheaper alternatives available from India and China. This is strongly driven by the perception of higher quality. Looking at the bigger picture, attempts to harmonise ASEAN region regulatory standards with Western markets may provide significant new sales avenues, especially, as costs rise and regulatory scrutiny intensifies in China and India. So in addition to the high growth in exports anticipated to Australia and New Zealand there may also be opportunities to grow in Europe and even North America.

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 Health Care Scheme. Predicted rises in income per capita will also drive sales of OTC medicines in the coming years. But, what is significant for overseas companies is the Government's act of loosening ownership restrictions on domestic firms. Consequently, foreign investors are now able to own 100% of partnerships; a figure that was previously 75%. Currently, 70% of drug manufacturers in Indonesia are domestic, but this figure is expected to decrease in the coming years due to foreign investments of circa \$20bn over the next 5-years^{vii}.

Philippines

The demand for healthcare in the Philippines is rapidly increasing for many of the same reasons as most other Southeast Asian countries. An aging population and subsequent increasing incidence of lifestyle-related diseases coupled with a rising GDP per capita will see increased consumer spending on pharmaceuticals. IMS Health forecasts that the Filipino market will see 4.5% annual growth over the next few years^{viii}, and is already the third-largest pharmaceutical market in ASEAN, just behind Indonesia and Thailand. In particular, 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 – which will see a basic level of healthcare available for all Filipinos in the future. New laws have also made it mandatory for public hospitals to provide generic drugs, whilst physicians are slowly beginning to endorse the prescription of generics to patients, having previously always opted to prescribe more expensive, branded alternatives. The rise in demand for high-quality generics is opening up a fantastic opportunity for both domestic and foreign players alike. The country is also well set with its manufacturing base, with 14 of the world's top 20 pharma companies owning manufacturing facilities in the 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, with the aim of reducing costs for consumers. These price controls will cap trade margins for drugs in the country, which will have a cascade effect on all players in the Malaysian pharmaceutical supply chain. The Pharmaceutical Association of Malaysia (Phama) has many 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^{ix}. Both foreign and domestic pharmaceutical companies will have to reconsider their business strategy if they are to retain their levels of profitability following the implementation of these drug price controls.

Singapore

In contrast with the majority of ASEAN countries, Singapore has a well-developed, mature pharmaceutical market –

built upon a country with high levels of personal wealth – with a reputation for high quality and even innovative manufacturing services. The Government here has further supported development with a number of schemes to drive innovation. Most recently, it committed to investing \$2.4bn to improve manufacturing and engineering in pharma as part of a 2020 'Research, Innovation and Enterprise' plan^x.

Additionally, a memorandum of understanding between the Agency for Science, Technology and Research, the National University of Singapore, and a number of large pharma companies was signed to launch the 'Pharma Innovation Programme Singapore'. This is a manufacturing initiative designed to boost the competitiveness of research companies in Singapore's public sector by supplying them with the expertise from big pharma players. The programme will help develop continuous manufacturing for API production, as well as implementing biocatalysis technologies for more sustainable production of complex and valuable chemicals.

Notable investments in the market from big pharma in previous years include GSK's \$130m continuous manufacturing facility, as well as WuXi Biologic's and Novartis' biologics plants, with the companies investing \$80m^{xi} and \$500m^{xii} respectively. 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^{xiii}.

Generic dossier approval timelines

For the countries that have defined dossier approval timelines there remains a high degree of variance for generic drug applications. A 2018 RAPS report examining 'the Drug Regulatory Landscape in the ASEAN region' estimates timelines range from just three months in Cambodia, six months in Malaysia and Laos, to nine months in Singapore and a year in Indonesia and the Philippines^{xiv}.

This Analysis

This report summarizes the findings of in-depth surveys carried out amongst 45 pharma executives from across six Southeast Asian countries, as well as international perspectives from European companies. It provides a holistic picture of recent trends, challenges and, most crucially, future opportunities for the pharma sector across the region.

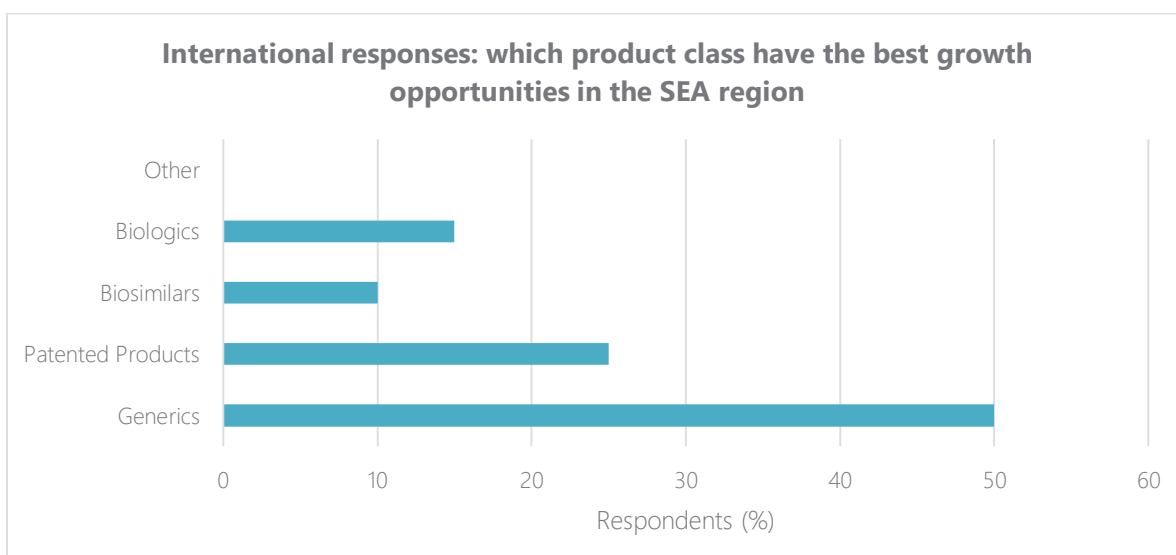
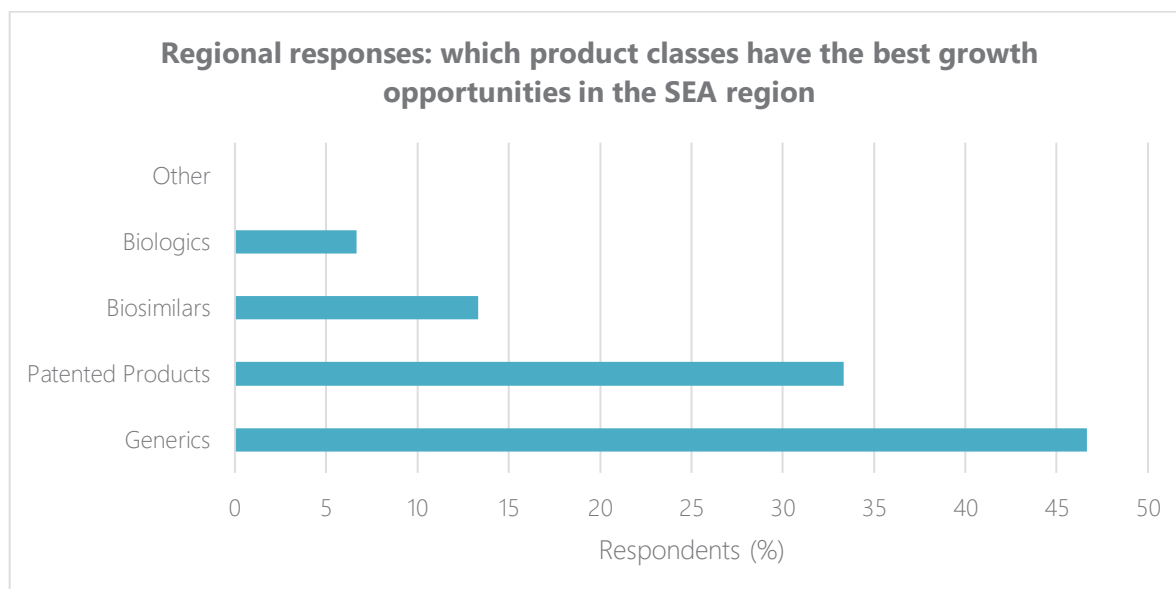
Fastest Growing Sectors

An analysis by sector of both domestic and international responses show generics and patented products are forecast to experience the fastest growth in Southeast Asia. Biologics and biosimilars (with the exception of 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 as well as newer emerging export markets for cheaper and branded generics offer the fastest returns. This is also where the majority of domestic and regional pharma companies have expertise.

Figure 1 (top): Shows the domestic response on which product class has the largest growth opportunities in the Southeast Asia region

Figure 2 (bottom): Shows the International response on which product class has the largest growth opportunities in the Southeast Asia region

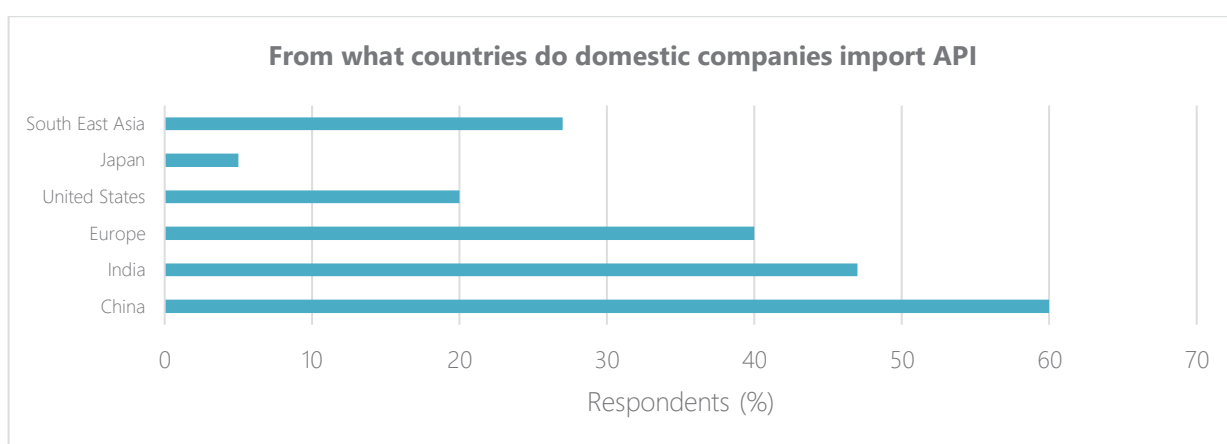


Domestic Response Summary

Interestingly, Southeast Asian companies sourced the majority of their API requirements from foreign sources. There was heavy reliance on both China (60%) and India (47%). However, Europe (40%) featured surprisingly strongly. The data is not conclusive but it might suggest a two-tier market for API sourcing; some using the lowest cost option from the big Asian providers with more expensive branded medicines produced sourcing some of their requirements from Europe. Most surprisingly, a

further 20% of respondents stated they sourced from the United States and 5% from Japan. Significantly, only 27% of companies sourced ingredients domestically, indicating that local economies are struggling to compete with the lower cost of the large regional manufacturers in China and India.

Figure 3: Shows the domestic response to regions/countries targeted for the import of APIs

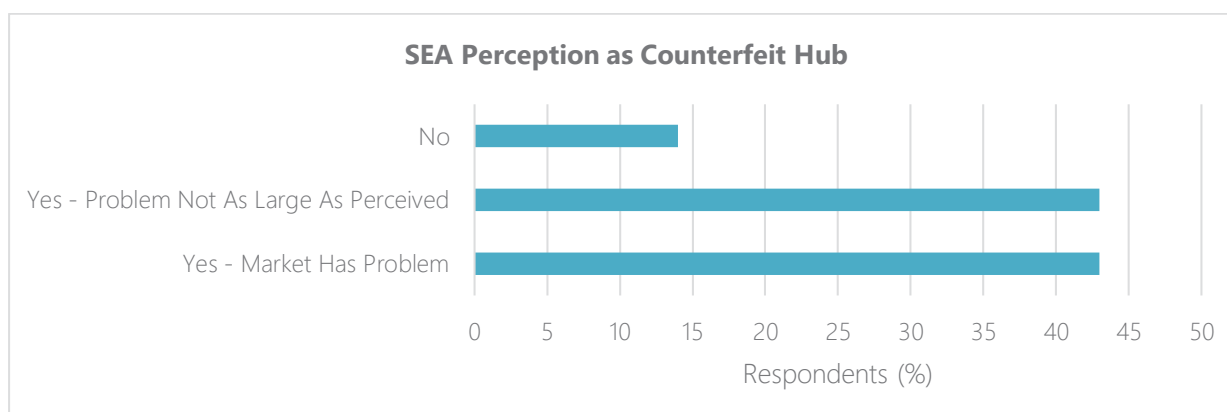


Countering Counterfeiting

The global counterfeit drug market is an extremely lucrative one, with the WHO valuing it at over \$30bn^{xv}. More worryingly, a recent study by the UN Office of Drugs and Crime (UNODC) found that Southeast Asian consumers spend as much as \$2.6bn on drugs that “may contain next to no API needed to cure the disease [in question]”^{xvi}. The perception of the Southeast Asian pharma market as a hub for counterfeit

pharma products is shared by the executives surveyed, with 86% agreeing with the statement. Significantly, however, half of the respondents agreed that ‘the problem does exist, but it’s not as large as perceived externally’.

Figure 4: Shows the perception of the SEA as a hub for counterfeit pharma products and if this perception is fair.



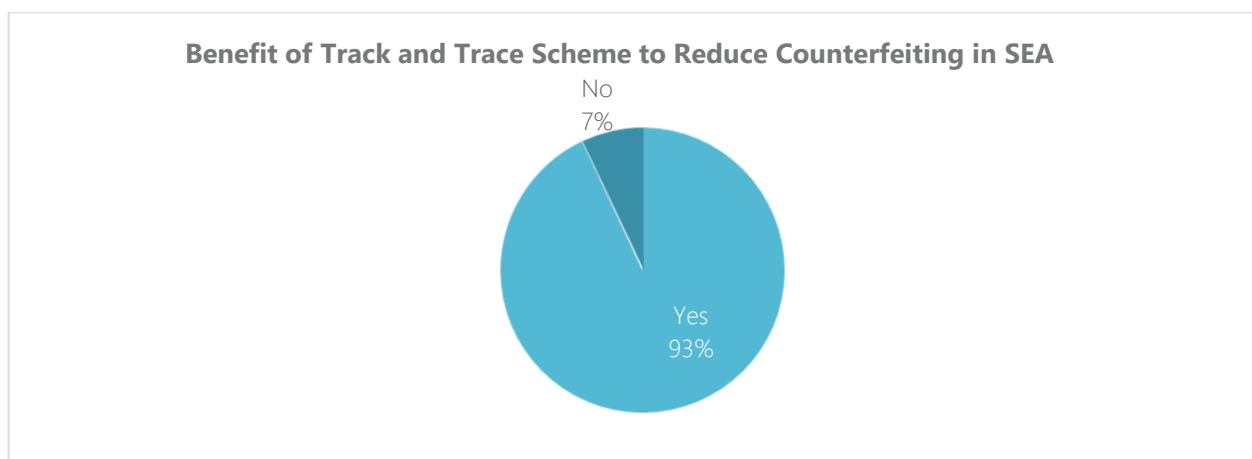
Governments across the region have implemented different solutions to address counterfeiting. Thailand tightened its patent approval regulations and introduced more rigorous enforcement of IP regulations. President Rodrigo Duterte of the Philippines ordered a major crack down on the makers and sellers of fake medicines. At a regional level, ASEAN Health Ministers highlighted the issue of online counterfeits in their annual meeting in September 2019.

A key finding from our research suggests the regional industry now favours introducing large scale counter measures, supply chain tracking and serialization. In fact, an overwhelming 93% of the industry experts surveyed believe that the Southeast Asian market would significantly

benefit from a Track and Trace-style scheme to reduce the space for counterfeiting in the region.

Data from the Pharmaceutical Security Institute (PSI) shows that of the 673 incidents of counterfeiting and illegal diversion in ASEAN from 2013 to 2017, 193 occurred in the Philippines, 110 in Thailand, 93 in Indonesia, and 49 in Vietnam^{xvii}.

Figure 5: Shows the percentage of SEA respondents that agree the region would benefit from a Track & Trace style scheme to reduce counterfeiting in the region

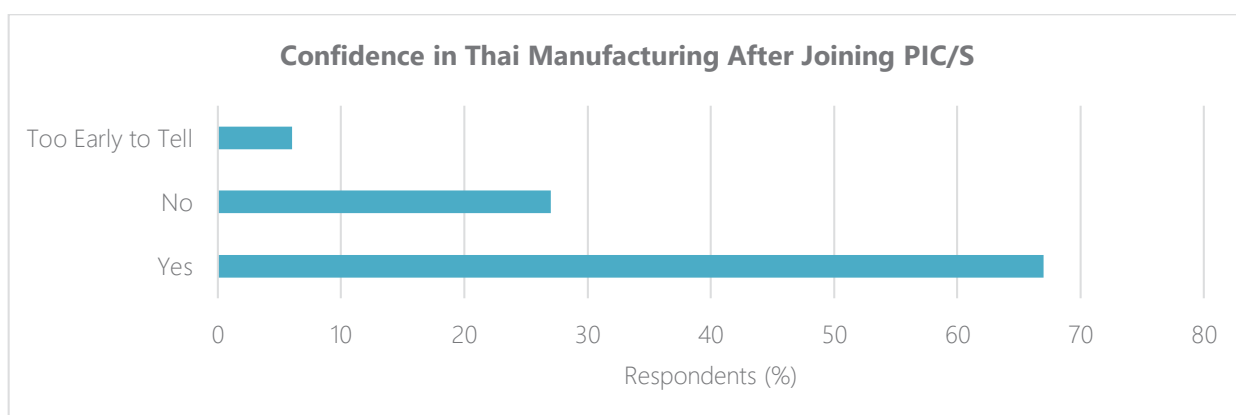


Is PIC/S manufacturing new opportunities?

Two thirds of respondents in the research stated that they now have greater confidence in Thai manufacturing after it joined PIC/S in 2016. Whilst many manufacturers are still adapting to meet standards and there may also be market consolidation – with smaller manufacturers struggling

to survive due to higher costs – it does appear to be strengthening the opportunity for those that have the ability to implement PIC/S standards^{xviii}.

Figure 6: Shows the increased confidence in Thai manufacturing after adopting PIC/S

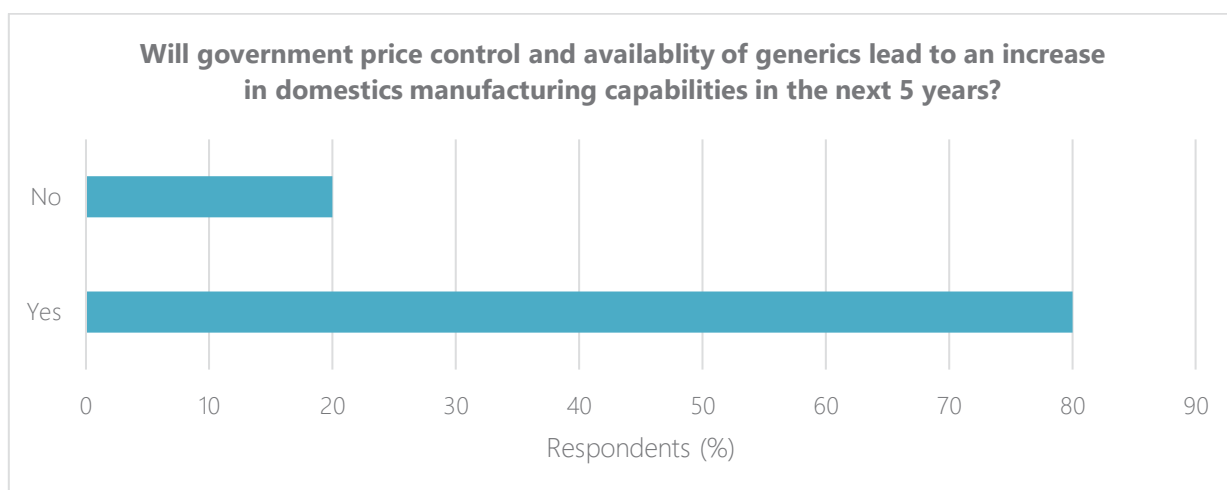


Internationally, joining PIC/S has also rapidly boosted Thailand's reputation. The PIC/S scheme has made local manufacturers a more attractive partner for international companies. 40% of the surveyed Southeast Asian industry experts said that they were more likely to work with small, local manufacturers after PIC/S than before PIC/S. One of the key benefits of PIC/S is that it is leading to a more harmonised industry across the wider region. A third of respondents believe that the introduction of PIC/S has increased the manufacturing standards of small manufacturers, making them more attractive trading partners both domestically and through ASEAN economies.

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, whilst most respondents gave PIC/S a glowing profile, there are concerns over lower margins stunting the market's growth potential initially: 47% believe that tighter regulations and cost restraints are already leading to lower profit margins. Significantly, 80% of respondents believe the desire to control drug prices and 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.

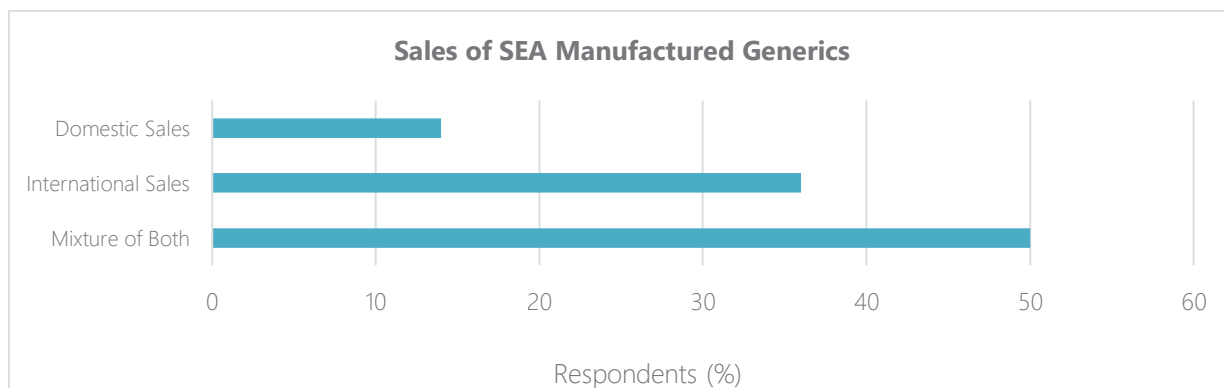
Figure 7: Shows if domestic manufacturing capabilities will increase over the next 5 years due to increase in generics and government price control.



Those able to achieve PIC/S standards will be able to sell much more widely than they have been able to in the past. While they can sell within the immediate economies regionally, achieving PIC/S standards also opens up the possibility of selling into western markets, a feat not achievable in the past. This is reflected in respondents' belief that growth in the sales of Southeast Asian

manufactured generics will come from either international sales (36%) or a combination of international and domestic sales (50%).

Figure 8: Shows where sales of SEA manufactured generics will come from.



The shift towards a more integrated regional pharma industry has resulted in more domestic manufacturers looking for international partners. All respondents stated they were looking to work internationally within the next 12 months, with 67% looking to utilize partners to help increase their company’s knowledge or aid the launch of pharmaceuticals made outside the region. Respondents

also cited the need to sell domestically-made products abroad and import APIs as other key reasons why they would look to collaborate with an international partner in the next 12 months.

Figure 9: Shows if domestic manufacturers are looking to work with any international partner in the next year

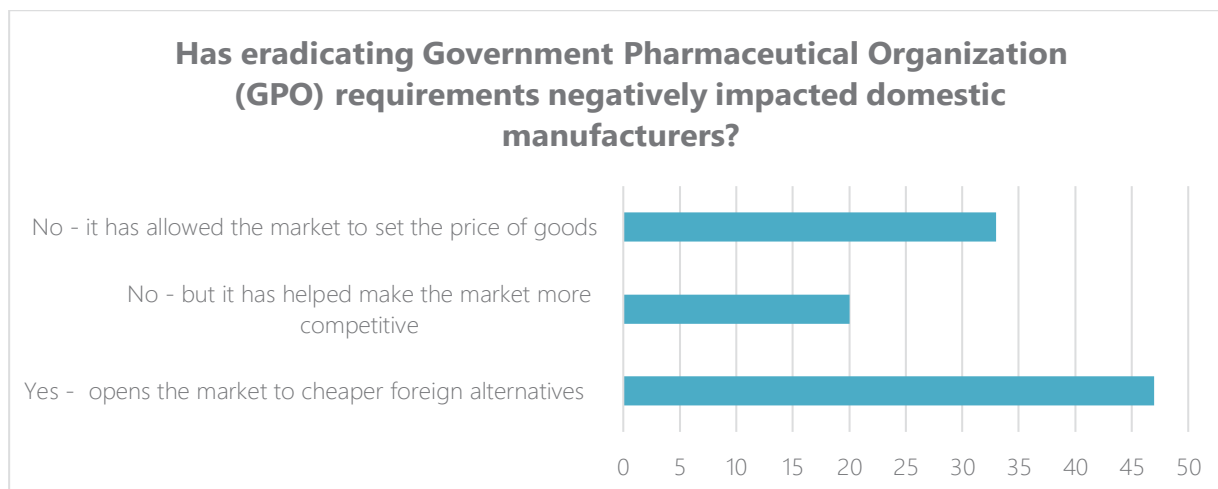


Thailand 4.0 – the birth of SEA’s newest pharma hub

With the Thai government looking to make Thailand a leading pharma destination in the region, the Thailand 4.0 initiative is being rolled out – a sector-specific policy seeking to transform the Thai economy. In fact, according to an IQVIA report the Thai pharmaceutical market is forecast to grow at a CAGR of 3.7% (±1.5%) between 2017 and 2022, reaching Bt178.1 billion by 2022 (circa \$6million)^{xix}. One major change predicted to accelerate the internationalization of Thai pharma 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 eradication of GPO requirements has helped the market become more competitive, however, 47% believe this will have an adverse effect on domestic manufacturers. Ultimately, it will enable the market to set its own prices and does potentially open up greater opportunities for imports.

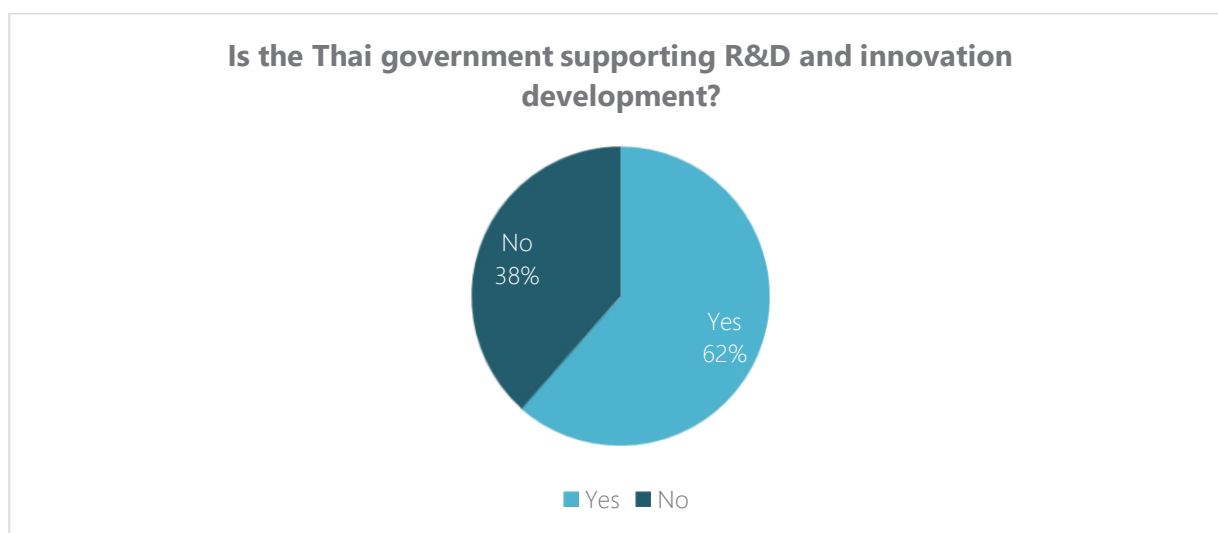
Figure 10: Shows if eradicating Government Pharmaceutical Organization (GPO) requirements negatively impacts domestic manufacturers



Another aspect of 'Thailand 4.0' is the transformation of the pharmaceutical industry into one driven by innovation. A plethora of biomedical and pharmaceutical innovation centres in Thailand – such as the Thailand Science Park and National Centre for Genetic Engineering and Biotechnology (BIOTEC) – have already been established. Looking ahead, the Eastern Economic Corridor of Innovation (ECCI) is an ambitious \$45bn project launched by the Government that aims to support investment in

the country. A primary objective of which is to help the scale-up of R&D through the provision of state-of-the-art translational research facilities^{xx}. The Government is funding the massive project through a mixture of both private and public sources and aims to attract significant foreign investment.

Figure 11: Shows confidence in Thai government supporting R&D and innovation development.



Thailand's Corporate Tax Exemptions are significantly increasing its appeal as an investment destination – particularly within the pharma industry – as agreed with by 80% of survey respondents. Prospective foreign investors would be able to benefit from a number of tax incentives, including exemption from or reduction of import duties on

machinery or R&D, as well as exemption from import duties on raw and essential materials imported for manufacturing for export^{xxi}.

Figure 12: Shows the impact of corporate income tax exemptions on Thailand as an investment destination.

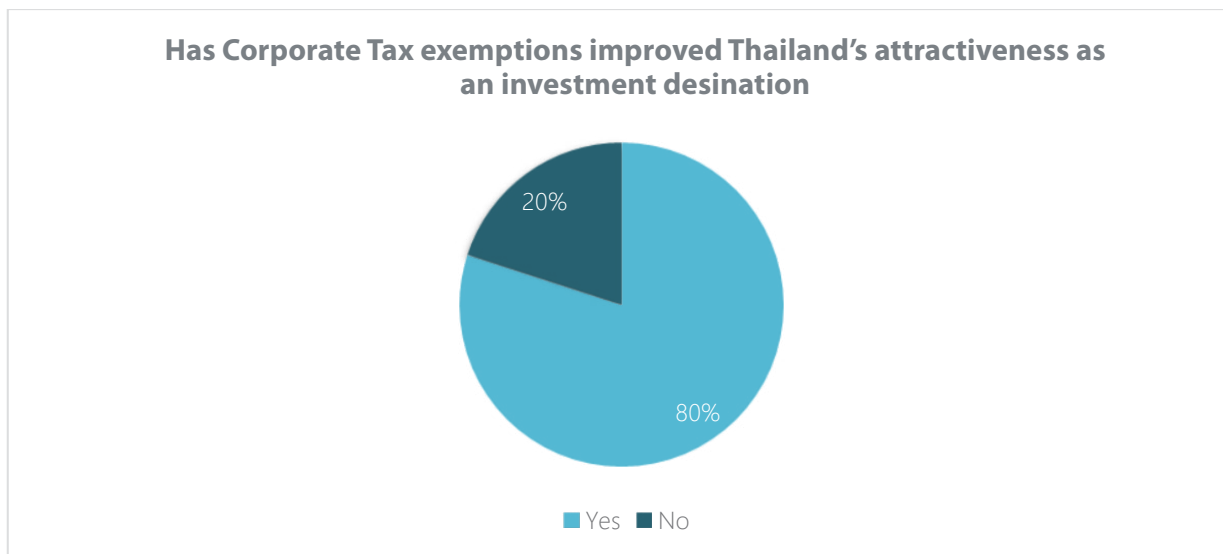
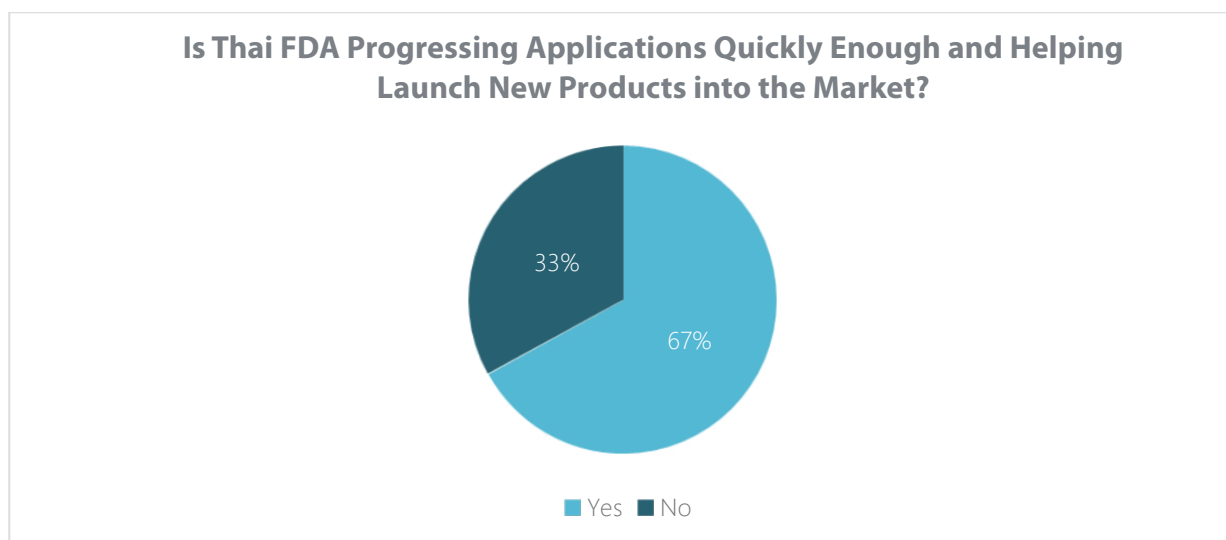


Figure 13: Shows if the Thai FDA is progressing applications quick enough and help aid launching new products into the markets.



International Response Summary

The International respondents we surveyed are bullish over their near-term prospects, with 88% of respondents citing a willingness to invest within the region, with a surprising 29% looking to invest in a new facility in SEA in the next 1-3 years. This reflects an increased confidence of international companies driven by multiple SEA countries joining PIC/S.

Other growth strategies highlighted by respondents include direct import, partnering with local manufacturers and importing directly into SEA.

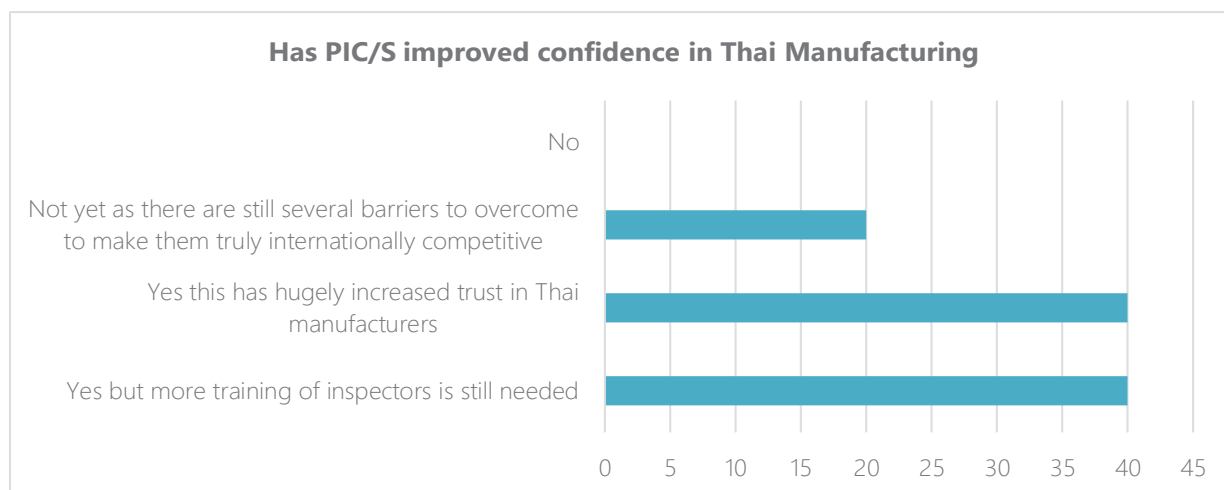
Figure 14: Shows the growth strategy appointed by SEA companies in the next 1-3 years.



Mirroring international willingness to invest, there is a significant upturn in confidence in Thai manufacturers amongst international respondents. In fact, an overwhelming majority - 80% of respondents - agreed that international confidence in Thai manufacturing has improved thanks to PIC/S. While 40% of respondents did temper their increased confidence with the view that 'increased training of inspectors was still an area of potential

improvement', and a further 20% remained neutral, that meant some 40% agreed strongly that their confidence had increased 'hugely' as a result. It's a clear indication that Thailand is well set for overall increase in export numbers and to markets outside of the immediate ASEAN region.

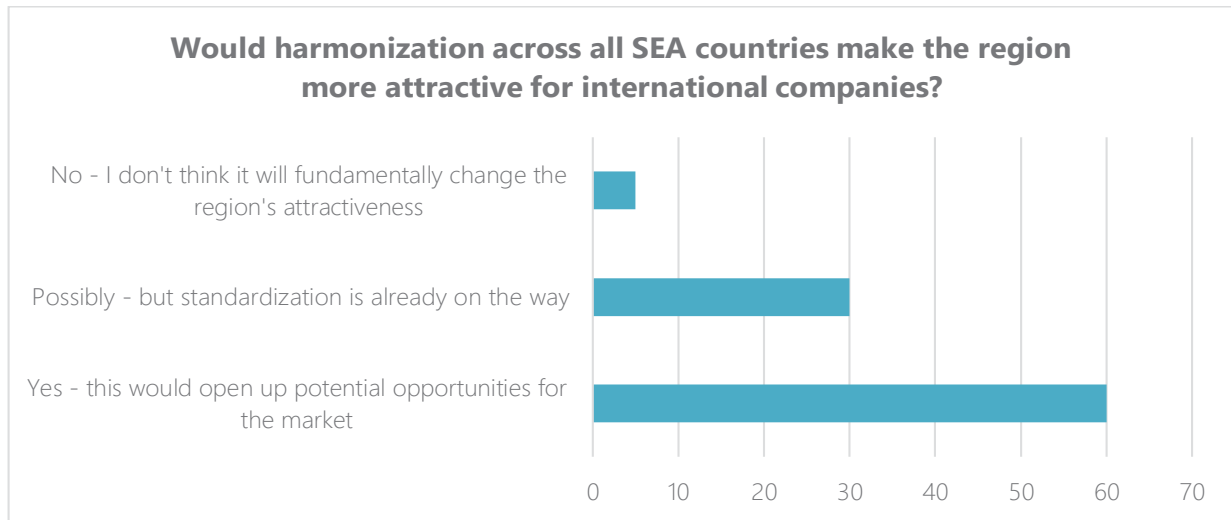
Figure 15: Shows the international confidence in Thai manufacturing after adopting PIC/S



In terms of potential drag factors; one major red flag when potentially investing in the SEA region is a discrepancy in regulations and standards across Southeast Asian 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 'agreed but that standardisation is already underway'.

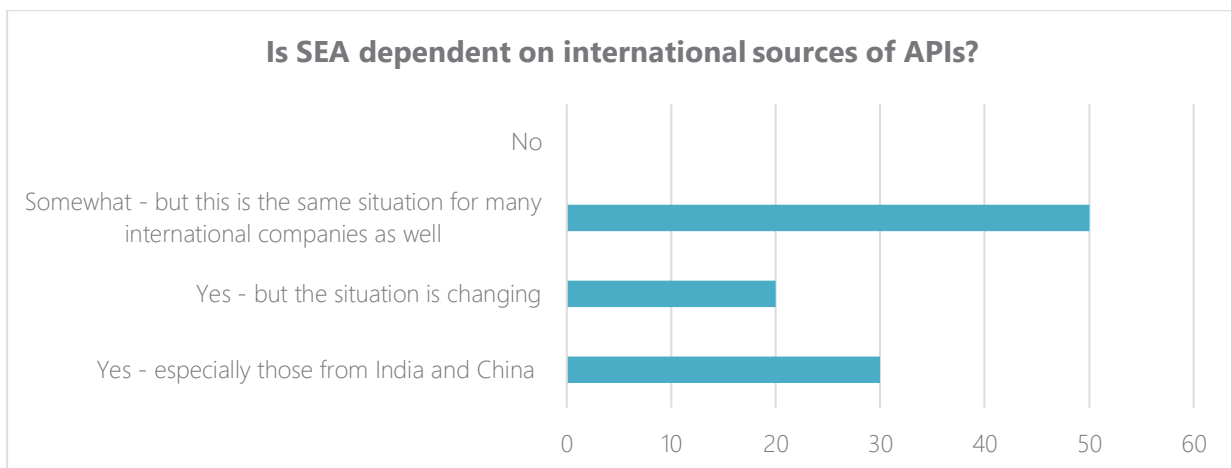
Figure 16: Shows the impact of standardized regulations and harmonization across all SEA countries on making the SEA region more attractive for international companies



Interestingly, one of the risk factors identified by domestic respondents was an overdependence on foreign APIs. However, international respondents seem largely unfazed by this, with half believing this is the same situation for many international companies, and a further 20% citing the situation is changing as the governments' in the region

encourage domestic/regional sources to mitigate against supply chain risk from China and India.

Figure 17: Shows if the SEA region is dependent on international sources of APIs



Conclusion

The overall results should be tempered by the relatively low number of respondents. However, our findings suggest the Southeast Asian region is improving quickly, and we may be on the cusp of a new dynamic for the pharma sector. The headwinds Southeast Asian markets have faced in the last few years appear to be easing at the same time as tailwinds accelerate. Significantly, the region's international reputation is improving quickly, and increased opportunities are opening up for bilateral trade. Generics and regional export opportunities look set for the best near term CAGRs with international companies now more likely to partner with local assets. Perhaps, the most significant finding and one that could potentially lead to Southeast Asia becoming a global hub for pharmaceuticals is the creation of European-style serialization system to combat the biggest area of potential concern for both regional and international companies – the prevalence of counterfeit

products. Our respondents both regional and international were nearly unanimous in their positivity for the impact such a scheme could potentially bring. Yet much more work still needs to be done to achieve true harmonization. For example, the Marketing Authorization process differs greatly across the region as does interpretation of national GMP standards. What is undoubtable, however, is that there is an increasing opportunity for regional exports – particularly generics. International pharma is also looking to move quickly to get a larger foothold in the region – either through partnerships or investing directly – and is predicted to grow quickly in the short and medium term. It also why there is such excitement around this year's CPhI Southeast Asia, as new partnerships and regional supply chains are now forming to sustain the the next stages of the region's pharma evolution.

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