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# Ingredients

## SOUTH ASIA

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# SEA APIs market dynamic & rapidly growing

DR SANJAY AGRAWAL

THE word "API," which stands for active pharmaceutical ingredient and refers to the ingredients or active pharmaceutical substances that can eventually be transformed into medicine, is frequently used in the pharmaceutical industry.

Organic substances called active pharmaceutical ingredients (APIs) are employed as the components of a finished pharmaceutical dosage form. In the pharmaceutical industry, high-quality chemical manufacture is crucial. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards "Q7A" (November 2000) and the Food and Drug Administration (FDA) of USA and current Good Manufacturing Practices (cGMPs) rules are used to establish the quality of APIs.

## Quality control of API Ingredients

The majority of nations control the production of APIs. These standards call for a holistic systems approach to ensure that an API is of the proper quality. All system components must be appropriately designed, validated, maintained, and operated to ensure that the API constantly satisfies quality standards. The method, the facilities, and the people make up the system's fundamental elements.

The compliance of APIs to pre-established requirements and whether they are generated following a documented validated method in a cGMP-certified facility are the two elements that determine the quality of APIs. The API must have the necessary chemical and physical properties to guarantee that it produces the desired pharmacological effect. The chemical characteristics describe the required purity and impurity limitations.

Clinical toxicological investigations are used to create impurity specifications, which are also based on the reasonable minimums that consumers and regulatory bodies demand. The physical properties must be present for effective pharmaceutical processing into finished dosage forms. Empirical data from formulation trials are used to make these determinations to create consistent, stable dose forms with sufficient bioavailability.

Like in almost any manufacturing company, quality control, and quality assurance department exist. These departments are typically integrated into a QM department these days. The check-test-decide mission of the QM department has evolved into a partnership with production and engineering to manage and enhance the quality of the entire process and system. The QM department still has the obligation imposed on it by legislation to release all APIs and drug products for usage and eventually to the market through its quality assurance division.

The QM department's or quality management department's tasks and actions are a part of the system that creates APIs, which is a part of prod-

uct quality. Most of the cGMPs mandate that the QM department is in charge of reviewing and approving production methods and any changes to them. This also applies to most reports, procedures, and controls necessary to ensure the quality of the process and product. For the QM department to efficiently carry out its duties, it must have enough laboratory facilities and well-trained and experienced personnel.

## Growing Market of API

The Southeast Asian market for APIs in the pharmaceutical industry is a rapidly growing and increasingly important market for pharmaceutical manufacturers and suppliers. This region, which includes countries such as Indonesia, Thailand, Vietnam, and the Philippines, is home to a large and rapidly growing population, and demand for pharmaceuticals is on the rise.

The pharmaceutical industry in Southeast Asia is expanding, and more clinical trials have been conducted recently. The region includes Malaysia, Singapore, and Thailand, three well-known study destinations, and has a population of about 620 million. The remaining seven ASEAN (Association of Southeast Asian Nations) nations include Brunei, Vietnam, Indonesia, the Philippines, Cambodia, Laos and Myanmar (Burma).

Asia has had exponential growth over the past 10 years and is currently the region most responsible for the pharmaceutical industry's growth, innovation, and future development. This study predicts that over the years 2021 to 2027, the ASEAN pharmaceutical manufacturing industry will expand by 12.8% annually, reaching a total addressable market value of \$148.3 billion. The rising prevalence of chronic illnesses, an aging population, and significant investments in research and development will fuel this growth.

Compared to markets from the United States and the European Union, those in Asia often have different industrial characteristics and a competitive environment. The winning procedure for the pharmaceutical industry in Asia often includes not only cutting-edge portfolios and pipelines but also inventive market access methods, cutting-edge business models, successful stakeholder engagement, and aggressive go-to-market tactics. China and Japan are currently the world's second- and third-largest pharmaceutical marketplaces, respectively, in terms of market size and scope.

Over the past 10 years, China, in particular, has experienced robust and steady annual double-digit growth, mostly due to continued infrastructural development, rising healthcare investment and coverage, and a supportive regulatory environment. With their enormous populations and powerful drivers, India, Indonesia, Thailand, and Vietnam also exhibit great potential. Asia is more significant than a rising market because it has become a crucial element of the global pharmaceutical ecosystem. Markets like Singapore, Australia, and Japan have

long been regarded as more in tune with the global industry, and more countries are following suit.

Vietnam spent most of the nations under consideration in terms of health spending as a proportion of GDP in 2014, at 7.1%. Despite this, the WHO says there are typically 7-8+ medical professionals and 25+ hospital beds per 10,000 Vietnamese inhabitants, much less than the global average of 15+ medical professionals and 30 beds per 10,000 people.

Indonesia had the lowest healthcare spending in the area, at 2.9% of GDP back in 2014. For a population of more than 250 million, upgrading and expanding its inadequate healthcare system will require significant investment. In 2022, it has significantly grown with 2500+ hospitals, and other pharmaceutical needs are fulfilled.

Brunei announced an earlier 9.2% reduction in its healthcare budget to prioritise responsible spending. With increasing budget allocations for infrastructure and technology, healthcare spending in Myanmar is rising.

## Conclusion

API is growing at a booming rate. The quality management for API ingredients is developing with time and great team efforts from top organisations. One of the major factors driving the growth of the Southeast Asian APIs market is the increasing prevalence of chronic diseases, such as diabetes and heart disease, in the region. As more people are diagnosed with these conditions, there is a corresponding increase in the demand for drugs and other treatments. This is particularly true in countries with rapidly aging populations, such as Thailand and Indonesia.

Another factor contributing to the growth of the Southeast Asian APIs market is the region's growing healthcare infrastructure. Many Southeast Asian countries are investing in expanding and improving their healthcare systems, leading to increased demand for a wide range of pharmaceutical products.

In addition to these factors, the Southeast Asian APIs market is also driven by several government initiatives and policies to promote the pharmaceutical industry's development. These include investment in research and development, tax incentives for companies producing APIs, and efforts to improve regulatory frameworks and standards.

Overall, the Southeast Asian APIs market is a dynamic and rapidly growing market that presents significant opportunities for pharmaceutical manufacturers and suppliers. As demand for pharmaceuticals continues to rise in the region, the need for APIs will also continue to grow. ○

*(The author is a leading pharmaceutical consultant)*



# ASEAN mfg to reach \$29120.1 mn by 2027

PARINA KUMARI AND VANDITA KAKKAR

**S**OUTHEAST Asia is a growing pharmaceutical market. The countries of southeast Asia, especially the members of the Association of Southeast Asian Nations (ASEAN: Brunei, Burma, Cambodia, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand, and Vietnam), have taken initial steps towards seeking more harmonised regulation of pharmaceutical and medical-device industries.

Healthcare has been designated a priority sector for the ASEAN countries from several years. With a population of more than 600 million, this market represents another rapidly growing emerging market. In general, the market has become more attractive in recent years as wages have risen and governments have prioritised healthcare sector growth.

According to a report published in "Pharmaceutical, statistic market forecast" the API market revenue is expected to show an annual growth rate (CAGR 2022-2027) of 0.35%, resulting in a market volume of US\$16.87 bn by 2027. In global comparison, most revenue was generated in the United States (US\$589.00bn in 2022). ASEAN pharmaceutical manufacturing industry will grow by 12.8% annually with a total addressable market cap of \$148.3 billion over 2021-2027. The ASEAN pharmaceutical manufacturing market was estimated to be valued at \$12541.9 million in 2020 which will be increased by 12.8%, with an estimated value of \$29120.1 million by 2027.

In a survey done by Global Data, Indonesia's pharmaceutical market is ranked as the largest market in the ASEAN regions, with the market value expected to hit IDR (Indonesian Rupiah) 141.6 billion (US\$10.11 billion) by 2021. Growth in the pharmaceutical industry is expected to reach 12-13 per cent per annum, said the report. Indonesia is fast becoming an attractive market for Indian pharma companies for their formulations and active pharmaceutical ingredient (APIs). It is home to 260 million people and one of the fastest growing pharmaceutical markets in Asia. The Thailand pharmaceutical market size was valued at \$6.4 billion in 2021. Thailand's pharmaceutical industry is Southeast Asia's second-largest pharmaceutical market, after Indonesia. Thailand's medical devices market size was valued at \$6.3 billion in 2020. The key export partners in the Thailand pharmaceutical market are Vietnam, Myanmar, Cambodia, Japan, and the Philippines. Vietnam accounts for highest percentage of the export business. In 2020, Cambodia also exported \$8.78M in pharmaceutical products, making it the 105th largest exporter of pharmaceutical products in the world. At the same year, pharmaceutical products was the 54th most exported product in Cambodia. The main destination of pharmaceutical products exports from Cambodia are: China (\$4.86M), South Korea (\$1.35M), Niger (\$1.12M),

France (\$581k), and Slovakia (\$249k).

Moreover, Malaysia has one of the ASEAN region's most developed pharmaceuticals and healthcare sectors. The Malaysian pharmaceutical industry has the capability to produce almost all dosage forms, including sterile preparations such as eye preparations, injections, soft gelatine capsules and time release medications. Malaysia is a significant exporter of medical supplies, especially for medical and surgical gloves in which Malaysia has a commanding global market share. Malaysia is a net importer of medicines but is gradually growing its profile as an exporter in the niche halal pharmaceutical segment.

Similarly, the Singapore market is fragmented with multinational companies dominating the space with major focus on research & development activities. There are 54 pharmaceutical manufacturers and 5,500 registered medicines as of 2017. Major multinational companies include GSK, Novartis, Roche, Pfizer, Bayer, AstraZeneca, Abbott, Baxter and Maccine. The pharmaceutical market has witnessed increasing advancement of innovative over-the-counter, generic, prescription and consumer health drugs. The Covid-19 pandemic is a double-edged sword for Singapore. While its economy has been hit by the global crisis, the island city-state is seeing an uptick in pharmaceutical manufacturing exports to countries looking to stock up on APIs.

In contrast, Myanmar pharmaceutical market valued at US\$456 million in 2017. This value is lower than that of most of the ASEAN countries, placing Myanmar below even Singapore in terms of absolute pharmaceutical market size, despite its much larger population (60mn versus 5mn). Looking ahead to 2022, the market is forecasted to touch \$ 656 million. Brunei announced a 19.2% health care budget cut earlier for 2021/2022 in a move to prioritise prudent spending. Although 2.6% of GDP was spent on healthcare in 2014, Bruneians re-

ceive free health care (and education, and subsidised food and housing). The number of hospital beds (3) and physicians (1.5) per 1,000 people is higher than the regional average. The Philippine health care spending was 4.7% of GDP in 2014, one of the lowest of South East Asia's major economies. But the government has committed to improve health care coverage evidenced by the Universal Healthcare Bill, passed into law in 2013, which promises health care insurance for all citizens of the Philippines, especially the very poor.

Southeast Asia also sees an increase of 11 per cent in overall competitiveness, up from last year. The findings provide a major boost for manufacturers in the region – particularly those in Thailand, Vietnam and Indonesia with significant growth expected in 2023. According to data from research and markets, Southeast Asia's pharmaceutical manufacturing industry will grow by 13% annually from 2021-2027, achieving a total market size of \$29.1 billion. This growth is being driven by high investment in research and development, a modernising manufacturing base and an overall increase in the chronic disease burden across the region. ○

*(The authors are from University Institute of Pharmaceutical Sciences, Panjab University)*



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