

South Asia's No. 1 Pharma News Weekly
R.N.I. No. MAHENG/2000/05366

CHRONICLE PHARMABIZ

A Saffron Media Publication ♦ Mumbai ♦ Vol.23 No.32



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Board decision to amend Sch P1 of Drugs Rules to rationalize pack size

size of 25 mandated for the Glyceryl Trinitrate Spansules (Long Acting) considering that the prescribed pack size may result in dose non compliance by the patients.

While deliberating the matter, the Board observed that as per the Rule 105, unless specified otherwise in Schedule P1, the pack sizes for Tablets/ Capsules where the number of Tablets/ Capsules is above 10, shall contain multiples of five. Where the number of Tablets (coated or uncoated), capsules (hard or soft gelatin) is less than 10, such packing shall be made by the integral number, it says,

Looking into the provision,

the Board recommended, "that the existing provision should be amended to provide that, for the pack size of Tablets/ Capsules where the number is above 10, the pack sizes of Tablets/ Capsules shall contain multiples of 5 or 7, considering the recommended dosage duration of the therapy".

The Board was apprised about the representation received regarding the requirement of 25's pack in the Schedule P1 [Rule 109] should be revisited and to be changed to 30's for all the Nitroglycerin timed release solid oral dosage forms (tablets and capsules) to avoid possible non-compliance to this life saving drug. ♦

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Promising landscape of South East Asian pharma

Dr. Sanjay Agrawal

THE healthcare and pharmaceutical manufacturing industry is highly dynamic, experiencing significant changes in its structure and operations. Companies in the pharmaceutical business are shifting from a fully integrated company structure to a model that emphasizes outsourcing projects, partnership initiatives, and contractual arrangements.

Organizations face constant challenges to stay efficient and effective in this competitive business environment. Additionally, as demographics change, the industry is transforming to meet consumers' evolving needs and demands.

The Covid-19 pandemic has fueled investments in digital research and development (R&D) and customer engagement, accelerating the transformation of healthcare delivery systems. The increased investment and deployment of home-based health technologies present new opportunities for biopharma companies to create value.

While the coming years are expected to bring many opportunities, recent reports forecast that the global pharmaceutical market will exceed \$1.5 trillion by 2023, growing at a compound annual growth rate (CAGR) of 3-6 per cent over the next five years. This growth rate represents a notable slowdown from the 6.3 per cent seen in the previous five years.

Trends and predictions

The pharmaceutical market in eleven countries in South Asia such as Brunei, Burma (Myan-

mar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand and Vietnam is fragmented.

East Asia, Brunei is poised to be a rising star in the pharmaceutical industry. With its strategic location and robust healthcare

services. Investing in Myanmar's pharmaceutical sector can not only yield financial gains but also make

Timor-Leste, a young nation with a striving healthcare system, presents a unique opportunity for pharmaceutical companies looking to expand their reach. The country's commitment to improving healthcare services and medication access creates a favourable environment for pharmaceutical investments. Timor-Leste's growing demand for quality pharmaceutical products makes it an emerging market to watch in the South East Asian region.



Aging populations and increasing healthcare needs are transforming the pharmaceutical markets in South Asia, presenting multidimensional opportunities along with new complexities and challenges for pharma market players

Aging populations and increasing healthcare needs are transforming the pharmaceutical markets in South Asia, presenting multidimensional opportunities along with new complexities and challenges for pharma market players.

The intense competition in pharma manufacturing across the region creates a dynamic environment to which industry players must adapt. Governments in these countries recognize the need for pharmaceutical advancements and are taking adequate measures to sustain economic growth.

Brunei

Nestled in the heart of South

infrastructure, the country presents promising opportunities for pharmaceutical companies looking to expand their regional presence. Brunei's commitment to innovation and healthcare advancements sets the stage for growth and collaboration in the pharmaceutical sector.

Burma (Myanmar)

With its vast population and evolving healthcare system, Myanmar holds immense potential as an emerging pharmaceutical market. As the country progresses towards healthcare reforms, opportunities arise for pharmaceutical companies to contribute to developing qual-

ity healthcare services. Investing in Myanmar's pharmaceutical sector can not only yield financial gains but also make

Cambodia

Cambodia, known for its rich cultural heritage, is also becoming a compelling destination for pharmaceutical investments. The country's efforts in enhancing healthcare infrastructure and growing demand for quality pharmaceutical products make it an attractive market for industry players. With an increasingly health-conscious population, Cambodia offers a promising pharmaceutical growth and development landscape.

Timor-Leste

Indonesia

As the largest economy in South East Asia, Indonesia holds tremendous potential in the pharmaceutical sector. With a growing middle class and increasing healthcare expenditure, the demand for pharmaceutical products is rising. Indonesia's bold regulatory reforms and focus on healthcare development pave the way for pharmaceutical companies to tap into this thriving market and cater to the diverse needs of its population.

Laos

Laos, a landlocked nation with a developing healthcare system, is poised for growth in the pharmaceutical sector. As the country invests in expanding healthcare services and improving access to essential medicines, opportunities arise for pharmaceutical companies to contribute to Laos' healthcare development. With its untapped potential and supportive government initiatives, Laos presents a promising landscape for pharmaceutical investments.

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Philippines presents dynamic market for pharma cos

CONTINUED FROM p.26
Malaysia

Malaysia, known for its robust healthcare infrastructure and progressive regulatory environment, offers a thriving market for pharmaceutical companies. With a strong emphasis on research and development, Malaysia has become a regional hub for clinical trials and medical innovation. As the country focuses on enhancing healthcare access and quality, the pharmaceutical industry benefits from Malaysia's promising market conditions.

Philippines

With its growing population and rising healthcare expenditure, the Philippines presents a dynamic market for pharmaceutical companies. The country's commitment to improving healthcare access and its robust pharmaceutical manufacturing capabilities create opportunities for local and international players. Investing in the Philippines' pharmaceutical sector enables companies to contribute to the nation's goal of providing quality healthcare.

Singapore

Renowned for its world-class healthcare system and research capabilities, Singapore offers a conducive environment for pharmaceutical innovation and growth. The country's supportive regulatory framework and strong intellectual property protection attract pharmaceutical companies seeking to establish a presence in Asia. Singapore's strategic location and vibrant life sciences ecosystem make it an ideal hub for pharmaceutical advancements and collaborations.

Thailand

Thailand, a regional leader in healthcare, presents a promising landscape for pharmaceutical investments. With its advanced healthcare infrastructure and strong manufacturing capabilities, the country offers a conducive environment for pharmaceutical companies to thrive. Thailand's commitment to research and development and its growing

medical tourism industry position it as an attractive destination for pharmaceutical players seeking to tap into the South East Asian market.

Asian pharmaceutical market. South Asia firms have established themselves as leaders in the global pharmaceutical landscape, with an annual

growth rate of approximately 14 per cent. This growth is primarily driven by the expanding economy and increasing per capita GDP.

than 200 countries. The country's pharmaceutical industry is a leading global producer of cost-effective generic medicines and vaccines, supplying

are even more reasons to be optimistic, given its socio-economic advantages. The nation is a popular outsourcing partner for international pharma at every value chain stage due to its expanding capabilities in contract manufacturing, R&D, and clinical trials. The countries have inherent advantages over many other nations, making them capable of exploring these opportunities and having the potential to become a worldwide hub for pharmaceutical outsourcing.

The South Asian pharmaceutical countries' appeal is thus expanding quickly in several ways, and many foreign businesses are increasing their investments there because they see India as a potential primary source of future sales. The global pharmaceutical business is changing and will undergo more soon, providing South Asian countries' drug industry an enormous opportunity to grow.

With its growing population and rising healthcare expenditure, the Philippines presents a dynamic market for pharmaceutical companies. The country's commitment to improving healthcare access and its robust pharmaceutical manufacturing capabilities create opportunities for local and international players

Vietnam

Vietnam's rapidly growing economy and increasing healthcare expenditure make it an emerging market of interest for pharmaceutical companies. The country's expanding middle class and the government's focus on healthcare reforms drive the demand for quality pharmaceutical products. Vietnam's strategic location, large population, and evolving healthcare system allow pharmaceutical companies to establish a strong presence and contribute to the nation's healthcare advancements.

Growth prospects

The pharmaceutical industry is significant in the South

growth rate of approximately 14 per cent. This growth is primarily driven by the expanding economy and increasing per capita GDP.

A few of the South Asian countries boast a well-established domestic pharmaceutical industry, with a strong network of over 3,000 drug companies and around 10,500 manufacturing units. It is the country with the most significant number of pharma plants compliant with US-FDA standards.

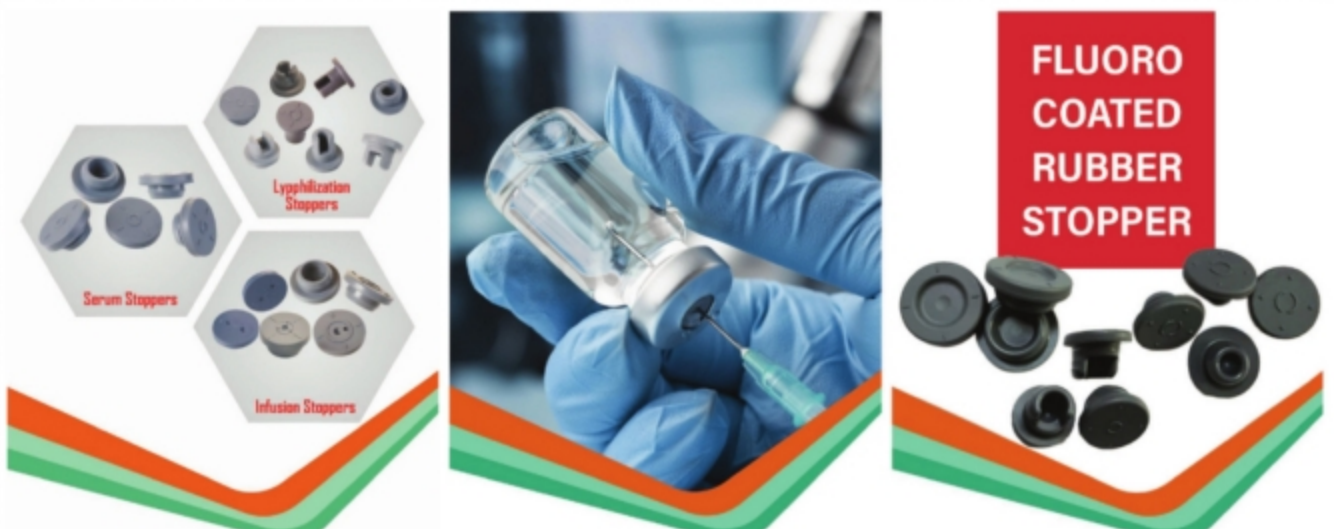
A few of the South Asian countries like India are widely recognized as a high-quality generic manufacturer worldwide, exporting half its pharmaceutical products to more

20 percent of the total global demand by volume and 62 per cent of the global demand for vaccines.

The country's capabilities in contract manufacturing, research and development (R&D), and clinical trials make it an attractive outsourcing partner at every stage of the pharmaceutical value chain.

As a result, the pharmaceuticals sector is poised for substantial long-term growth, and the domestic market appears to offer opportunities for global market participants seeking to diversify, expand, and introduce new products. Although it has long been a strong competitor in the pharmaceutical industry, there

(The author is leading pharmaceutical consultant and Editor-in-Chief of IJMToday)



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