



## ||| SPECIAL FEATURE |||



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### Indian pharma SMEs

# In the centre stage

In recent years, the Indian pharmaceutical industry has been witnessing phenomenal growth rates. The small & medium enterprises (SME) sector, in particular, has played a significant role in developing and shaping India's this stature. In fact, SMEs account for around 87 per cent in production by volume and 40 per cent by value in the pharma industry. Thus, these cost-effective vital resources of skill, knowledge and employment, are definitely in the centre stage. **KTP Radhika Jinoy** explores the potential of Indian pharma SMEs, emerging opportunities and future prospects.

**I**ndia is the world's fourth-largest producer of pharmaceuticals by volume, accounting for around 8 per cent of the total global production. Due to the increase in consumption and strong export market, the Indian pharmaceutical industry has been witnessing phenomenal growth in recent years. The industry has seen tremendous progress in terms of infrastructure development, technology and the wide range

of products manufactured. Indian players have proved their ability to produce cost-effective drugs with their state-of-the-art manufacturing facilities, thus increasing exports from the country. Thus, with its low-cost manufacturing, high-quality research & production facilities and educated personnel, the Indian pharmaceutical industry presents a competitive threat as well as partnership opportunities.

Small and medium pharma enterprises (SME) have played a key role in driving the growth and current status of the Indian pharmaceutical sector. In terms of number of units and employment generation, the SME sector is at the forefront. Gaurav Khungar, business head – Pharmaceuticals, KPMG, says, “Small and medium scale units have played a crucial role in the growth story of the Indian pharmaceutical industry and form an integral part of the sector. The Indian pharmaceutical industry is highly fragmented and estimated to have 9,456 units in the SME segment, which account for around 87 per cent in production by volume and 40 per cent by value.”

Navroz Mahudawala, associate director, Life Sciences Practice, Ernst & Young, also agrees on the significant role played by SMEs. He avers, “The Indian pharmaceutical sector derives its strength from the SME sector, as SMEs form an essential part of the supply chain for the larger players.”

### Key strengths

In India, pharma SMEs are cost-effective vital resources of skill, knowledge and employment. It is they who provide accessible essential drugs to the country. “Contributing to about 35 per cent sales of the pharma sector, SME players generate a turnover of around Rs 35,000 crore. In India, SMEs are mainly focussing on manufacturing, niche marketing and contract research & manufacturing services (CRAMS) including clinical trials, supply to hospitals and the World Health Organization (WHO),” asserts Daara Patel, secretary-general, Indian Drug Manufacturers’ Association.

SMEs have strong re-engineering skills, which help them provide a low-cost yet high-quality value proposition. Increasing opportunities in the generics pharmaceutical market, both domestic and exports are fuelling the growth of this sector. Khungar says, “Pharmaceutical SMEs in India

### Gaurav Khungar

business head – Pharmaceuticals, KPMG



SMEs can play a strong role in the R&D area. The sector has been asking for various kinds of fiscal incentives and tax sops in order to stimulate investments in innovations and R&D beyond the current tax deduction.

have traditionally been less focussed on exports in comparison to large domestic firms. However, now they have become preferred partners for the supply of active pharmaceutical ingredients (APIs) and finished dosages for Indian as well as foreign pharmaceutical firms.”

As a result, SMEs have to compete globally, where one has to be innovative and has to actively advertise. However, the robust and focussed business models & plans are helping pharma SMEs in their growth momentum. Besides, the rapidly emerging CRAMS market is an open and lucrative outsourcing business space for SMEs to cash on and leverage on their current cost arbitrage in collaboration with large local & global pharmaceutical companies. Another is the entrepreneurial leadership that the sector enjoys. Agrees Tapan Ray, director general, Organisation of Pharmaceutical Producers of India, “High level of entrepreneurial zeal and low operational costs across various

pharmaceutical business processes help pharma SMEs grow and prosper.”

### R&D activities

The Indian industry has been evolving since the beginning of the new post-patent era. R&D departments are moving away from reverse engineering in favour of developing novel drug delivery systems and discovery research. The SME sector is also trying to focus on conducting R&D. However, for better R&D, one requires high investment, which is what SMEs lack. To promote R&D in SMEs, the government needs to come up with incentives and promotion programmes. At present, the government is providing tax deduction to promote R&D, but according to industry experts, this is not sufficient. Khungar explains, “SMEs can play a strong role in the R&D area. The sector has been asking for various kinds of fiscal incentives and tax sops in order to stimulate investments in innovations and R&D beyond the current tax deduction. The tax reduction demands of SMEs are to the tune of

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### Daara Patel

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150 per cent on R&D spend, as the current percentage is not enough to stimulate investments in this arena."

So, at present, only a small per cent of SMEs are really focussing on R&D. The government is planning to offer more sops for the sector. Ray says, "In the recently held 'India Pharma Summit', the Department of Pharmaceuticals of the Government of India announced that the government is planning to set up a venture fund to promote R&D in the pharmaceutical sector, especially for SMEs. This will be a close ended fund with a corpus of around Rs 2,000 crore. The initiative will have active stakeholders both from the government as well as from industry. The broad outline will emerge in the next two months and the fund will be operational in about three years. Moreover, incentives for R&D by way of extending the weighted deduction at the rate of 150 per cent of the expenses on R&D for the next five years and duty exemption for imports of specified machinery used for R&D purpose will help the sector to augment R&D capabilities."



### Existing constraints

Although the economic and social importance of the SME sector is well recognised, it is a fact that the sector still is not receiving its due credit in some areas, especially in terms of finance. For innovation and growth, an SME require adequate funding. Moreover, for technical upgradation to maintain a competitive edge, SMEs need sustained investments. "One of the key impediments for the pharma SME sector has been the lack of financial support. Capital constraints have been impinging on the sector's development right from setting up of operations to technical upgradations in line with dynamic international requirements and procedures. Restricted access to resources is also proving to be a deterrent to their endeavour to move up the value chain, as it is compelling SMEs to put R&D and innovations on the backburner," avers Khungar.

Besides financial constraints, the SME segment is also challenged by the need to create visibility and demonstrate credibility to prove their global competitiveness. But sales and marketing activities are becoming increasingly expensive in terms of cost of skilled field staff and modern day marketing tools. Another challenge facing the sector is that there is a lack of awareness and knowledge about procedures & regulations. "According to estimates, only around 30 per cent of SMEs in the pharma sector are GMP-certified. Another drawback is that

SMEs are seen to have limited ability to attract and retain talent. Moreover, SME players are more vulnerable to market fluctuations as compared to larger players, owing to their restricted ability to adapt to changing market conditions," adds Khungar.

The pharma industry is highly competitive. Only innovation and new solutions will enable SME players to survive in this market. Ray explains, "SMEs that operate only in the highly competitive domestic market with manufacturing and marketing of low price formulations will face more challenges. And these challenges will be even more with SMEs who do not have adequate means to face the rapidly changing business environment or falter in choosing the right business models, as applicable to them. There should be regulatory conformance to more rigid product quality norms to offer better quality of medicines to the patients. Also, there should be sustained investments towards technical upgradation to maintain a competitive edge in terms of the manufacturing cost," says Ray.

One of the main challenges faced by pharma SMEs is the implementation of information technology (IT) tools at an affordable cost. Software tools would help SMEs in computer-aided drug designing, better understanding & management of intellectual property rights and licensing issues. "But most players continue to under-invest in IT systems and good accounting practices," avows Mahudawala.

### Measures to improve

There are various measures that SMEs can adopt to overcome the hurdles. First, they should build competencies in areas that do not require significant capital infusion, but help differentiate them from the competition. Khungar elaborates, "These areas can be manufacturing of certain types of dosages or APIs that are difficult to manufacture and reach the market. They should also try to

collaborate more with other SMEs to leverage on their capabilities.”

The Department of Pharmaceuticals has been taking steps to support SMEs through various incentives and facilities. Some of them, such as, the credit linked capital subsidy scheme (CLCSS) to SME pharma units, will enable SMEs to upgrade their facilities as per the revised Schedule M. The development of pharmaceutical SEZs is one such step with identification of around 18 pharmaceutical SEZs, which will offer advantages like availability of developed infrastructure, market access and exports, along with various tax incentives.

Pharmaceutical associations and organisations are also working for the welfare of SMEs. Patel says, “It is a matter of pride that many SMEs of yester years have become national companies now. We coordinate with the government, especially the Department of Pharmaceuticals and MSME Ministry on the various support initiatives that need to be taken for the progress of the SME sector. We have also raised our voice whenever government organisations have imposed unfair limitations to their procurement policies, such as a minimum turnover of Rs 100 crore, top 100 rankings, etc. Also, the Competition Commission of India is trying to ensure a level playing field. We have proactively submitted detailed representations to the MSME Ministry and Planning Commission for providing subsidies under the CLCSS scheme for machinery, equipment & tools as required by Schedule M.”

The Department of Pharmaceuticals has organised a detailed list of 179 items along with the MSME Ministry to provide subsidy under the CLCSS. Also, the Department of Pharmaceuticals, MSME Ministry officials, bankers and SSI manufacturers are working together to provide subsidy to SSI units. Keeping in view the difficulties experienced by SMEs in the pharmaceutical sector, the Department

## Tapan Ray

director general, Organisation of Pharmaceutical Producers of India



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has also proposed a Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS). Implementing the measures under the Schedule M to the Drugs and Cosmetics Rules, WHO-GMP and other international norms relating to good manufacturing practices and requirements of premises & equipment causes additional financial burden for SMEs. The proposed scheme will help SMEs for technological upgradation. The scheme provides for interest subsidy in respect to 5 per cent of the loan taken by the SMEs for implementing Schedule M. The Department is in the process of seeking necessary approvals for this scheme.

“The advent of the revised Schedule M has triggered the modernisation of SME pharmaceutical plants. Although SMEs had to undergo financial hurdles, many of them have overcome the same and have created pharmaceutical plants conforming to good standards. These plants are likely to cater to outsourcing in a big way under contract manufacturing. SMEs are likely to play an increasing role in contract manufacturing to major Indian and multinational companies,” states Patel.

### MNCs of tomorrow

SMEs of today are MNCs of tomorrow. Mahudawala seconds, “The core of the Indian pharma sector is the SME sector, which will continue to prosper.” Experts say that the pharma SME sector will continue to be one of the most important growth engines

of the Indian pharmaceutical industry in future too. Indian SMEs, which have now been exposed to global markets upon overcoming the challenges, are well-positioned to capture a plethora of opportunities that exist in areas like contract manufacturing and the exports market, as well as segments like biopharma and contract research.

Ray adds, “The future of pharma SMEs in India seems to be quite good, provided they choose the right business model for growth. However, it is worth noting that the SMEs will now face many more new challenges related to the globalisation process of the Indian economy and markets, along with regulatory and social needs for improved quality of medicines and conformance to more stringent environmental & safety standards.” So, for enhancing the SME sector and its growth, a collaborative approach from both large domestic as well as global players will be of utmost importance. 



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