

The Changing Scenario of SME in India

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The Indian Pharmaceutical Industry is undergoing tremendous change in terms of infrastructure development, technology base and the range of products manufactured. With its low-cost manufacturing, educated personnel, quality research and production facilities, it has been witnessing phenomenal growth in recent years, driven by rising consumption levels in the country and strong demand from export markets. The small and medium pharma enterprises (SMEs) have played a crucial role in boosting the overall growth of the Indian pharmaceutical sector. SMEs account for around 87 percent in production by volume and 40 percent by value in the pharma industry. Pharma SMEs are cost-effective resources of knowledge, skill and employment. In today's scenario, the increasing opportunities in the generics pharmaceutical market, both domestic and exports are empowering as well as encouraging. It is they, who provide the accessible essential drugs to the country. This section is playing an important role in the economic and social development of the country by discovering, developing, manufacturing and providing the drugs to the country and forming an essential part of the supply chain for the larger sector.

Being a knowledge-centric industry, it has a great potential to extensive growth. Pharmaceutical SMEs in India have been less focused on exports but are the partners for the supply of active pharmaceutical ingredients (APIs) and finished dosages for Indian as well as foreign pharma units. SMEs have to compete globally, where they have to be compulsively innovative. Though the economic and social importance of the SME sector is well recognized yet the fact remains that the major hurdle for the pharma SME sector has been the lack of adequate financial support. The problem of funding plaques the SMEs as continuous and huge investments are needed for innovation, R&D and overall growth. Besides financial constraints, the SME segment is also challenged to prove their global competitiveness. One big challenge faced by SMEs include the lack of awareness and knowledge about procedures & regulations, achieving stricter quality norms, consistent technical up-gradation to maintain a competitive edge in line with international requirements and marketing.

The Government of India has taken initiatives to upgrade SME infrastructure. The department of pharmaceuticals has been taking steps to help and support SMEs through various incentives and facilities. With the help of credit linked capital subsidy scheme (CLCSS), SMEs can upgrade their facilities as per the revised Schedule M. The advent of the revised Schedule M has triggered the modernization of SME pharmaceutical plants. Although SMEs had to face financial hurdles, many of them have overcome the same and have created pharmaceutical plants conforming good standards. Certain domestic Pharmaceutical associations and organizations are also working for the welfare of SMEs. Linkages between these firms and pharmaceutical research and educational institutions for technical upgradation related to R&D as well as quality control have been established. The government has

taken a step in this direction through the efforts of National Institute of Pharmaceutical Education and Research (NIPER-S) to act as an intermediary organization in providing technical support to small firms. Five more Pharmaceutical Institutes of National level have been setup at Hyderabad, Kolkata, Ahmedabad, Guwahati and Raibareilly.

NIPER-S is the first national level institute in pharmaceutical sciences with a prime objective of becoming a centre of excellence for advanced studies and research in pharmaceutical sciences. NIPER-S has been conducting GMP and GLP training programs for the pharmaceutical professionals in India for the last few years. The trainings were initiated under the 'Capacity Building Project' sponsored by the World Bank for the staff from government and private testing laboratories, regulatory bodies and analytical as well as production staff from small and medium Pharmaceutical industries (SMPIs). Later, the Department of Pharmaceuticals, announced setting up of a dedicated centre for SMPIs. In year 2009, Small and Medium Pharmaceutical Industries Centre (SMPIC) was setup at NIPER-S aiming at creating synergy between industry and academia. SMPIC provides forums for the manufacturers, regulators and suppliers to come together to discuss common interest and new technologies. SMPIC is well known for its trainings and educational programs. Under the program, hands-on practical training sessions on sophisticated instruments like analytical HPLC, GC, FT-IR, UV-Vis Spectrophotometer, HPTLC and AAS, designed in consultation with SMEs, are conducted on a regular basis (training calendar for the year 2012 available on www.niper.nic.in). One and two day seminars on good manufacturing and laboratory practices, 'Documentation', 'Validation', 'Risk Analysis', 'Current Good Manufacturing Practices' and 'Export Registration of Pharmaceutical Products' were successfully organized during the period 2009 to mid 2012.

Distinguished institute like NIPER is conceived to provide leadership in pharmaceutical sciences and related areas not only within the nation, but also to the foreign countries. I am honored to be associated with this Institute and privileged to be in Editorial Board of the renowned journals of OMICS Group Incorporation.

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