

Growing Focus on Domestic Manufacturing in the Pharmaceutical Sector in India

*Over the past decade, the pharmaceutical industry in India has witnessed increasing investments flows for research and development, innovation as well as a keen interest from foreign manufacturers in setting up manufacturing units in the country. The trend is supported by the adoption of favourable policies and initiatives in the sector after undertaking stakeholder discussions to enable partnership with the industry. **Dr. Milind Antani and Tanya Kukade** discussed the overview of the Indian pharmaceutical sector and growing focus on increasing domestic innovation and manufacturing.*

The developments outlined such as the release of the draft National Pharmaceutical Policy, 2023 and revision of the Good Manufacturing Practices are meant to bring domestically manufactured pharmaceutical products at par with the global standards. These developments in the sector are supplemented by the focus of the government on the Make in India initiative which seeks to encourage domestic manufacturing and projecting India as the global manufacturing hub. The objectives of the government under the initiative adopted in 2014, and subsequently refurbished in 2018 are being further supplemented by internal policy changes to mould the industry standards and harmonizes them with international standards while also to encourage foreign investment in the country. This coupled with the government allowing 100% foreign direct investment in the pharmaceutical sector is a development with potential for tremendous growth of the sector.

Given that manufacturing forms the backbone of development for every sector, there is strong focus on increasing domestic innovation and manufacturing in each sector in the country. The Government introduced various production linked incentive (PLI) schemes such as the PLI Scheme for Promotion of Domestic

Manufacturing of critical Key Starting Materials (KSMS) / Drug Intermediates and Active Pharmaceutical Ingredients (APIs) to cater to the increasing focus on the sector by incentivising local production and development. The PLI schemes coupled with the Make in India initiative aid the objective of strengthening the pharmaceuticals industry in the country.

In an effort to increase the scale of manufacturing in India and to promote the country's ability as well as to make the country self-sufficient, the Make in India initiative is primarily implemented by the Department for Promotion of Industry and Internal Trade (DPIIT). The DPIIT overlooks the public procurement process and has released the Public Procurement (Preference to Make in India) Order, 2017 or the General Order which prescribes the requirements for suppliers to be eligible to participate in the public procurement process basis the value added to the product in India. The nodal ministry of each industry is empowered to prescribe the requirements and qualifications for suppliers to be eligible to participate in the tendering process for the government requirements basis the local manufacturing capacity for the products and the extent of local competition.

The nodal ministry for the pharmaceutical industry is the Department of Pharmaceuticals (DoP) under the Ministry of Chemicals and Fertilizers. The DoP has notified higher local content requirements for pharmaceutical products under the Public Procurement (Preference to Make in India) Order, 2017 - Goods and Services in Pharmaceutical Formulations. The public procurement orders place heavy reliance on local value addition which may take the form of manufacturing, research and development, assembly, etc.

The steady growth of the industry as well as the adoption of the policies by the Government give a flavour of the intended approach and objective to encourage domestic manufacturing in the country and to cater to the growing global demand for goods and services. The Indian market has fair demand as well as capacity to cater to domestic as well as global markets. India has also witnessed a keen interest on behalf of global pharmaceutical companies, seeking to either establish operations in India for research and development, manufacturing or distribution or to enter into collaborations to meet the unique eligibility requirements under the procurement orders adopted by each nodal ministry.

India's low-cost research and development abilities help companies optimize costs in a shrinking economy. For a trans-national entity seeking a presence in India, whether directly or through contractual arrangement, structuring of the investment arrangement from a tax and regulatory perspective is very critical. This is especially true because the Indian pharmaceutical market has become the hotbed of manufacturing activity.

The impact of the Make in India initiative is expected to yield positive results for the pharmaceutical industry in the coming years. The initiatives and policies of the government to encourage domestic manufacturing in the pharmaceutical sector are likely to reduce the reliance of the industry on imports of drugs and APIs, making the sector self-sufficient.

The industry requires policy interventions to support the adoption of new pharmaceutical technologies through onboarding of stakeholders in the sector on the

Ayushman Bharat Digital Mission ecosystem to provide a platform for collaboration and exchange of knowledge and innovations. There is a need for collaborative efforts to be undertaken by the industry players to meet the broader initiatives of universal healthcare access, innovation-driven economic growth, and sustainable development. Continued stakeholder discussions and recognition of innovative developments in the sector are likely to steer the growth of the pharmaceutical industry in a positive direction. ■

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