

Pharmaceuticals: Consolidated Issue Summary

S.No.	Areas	Issues
1	Scalability	Fragmented nature of the Indian pharmaceutical industry means that only few companies are large enough to bear the transactions costs associated with compliances attached with entry regulations of the developed markets.
		Important facets of pharmaceutical industry such as intellectual property creation, facility design and maintenance, global regulatory affairs, legal compliances, etc. are being conducted by limited large players
		Lack of Cold Storage space & facilities suited to specific pharmaceutical products, with automated humidity & temperature control mechanisms
2	Cost Efficiency	Stringent pricing regulations affecting the profitability of pharmaceutical companies.
		Rising prices of sugar leading to overall increase in production costs.
		Land locked regions like Pune, Hyderabad, Indore etc. which contribute majority share of Indian Pharmaceutical trade incur higher costs of transportation
		Lack of availability of petrochemicals used for manufacturing of bulk drugs in India resulting in reliance on imports.
		Lack of availability of reference standard products as per Indian Pharmacopeia (IP). Thus while more than 1000 molecules are being manufactured or marketed in the country, IPC has reference standards for about 200 products only, resulting in dependence on imports for these batch specific and time limited reference products. This increases the overall cost of testing.
3	Productivity Optimization	Lack of advanced lab and related infrastructure for drugs testing, especially in segments like antibiotics.
		Low investments in innovative R&D continue to be a major weakness of Indian Pharmaceuticals industry.
		Inadequate medical devices and equipment industry. Critical equipment like analytical instruments etc. is not indigenously available.
4	Quality Excellence	Lack of ability to compete with MNCs for discovery of new drugs, research & commercialization of molecules on a worldwide basis.
		Lack of resources with the Central Drugs Standards and Control Organization (CDSCO) leading to delays in clearances for new drug trials, pharmacovigilance and assistance to the willing industry members
5	Sustainability	Stringent pricing regulations affecting the profitability of pharmaceutical companies.
		Lack of awareness of global testing standard for drugs among Indian SMEs
		Lack of proper regulatory framework for bio-similar drugs