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Regulate Pharma to be Truly World Class

It is India's toehold in advanced manufacture

Regulation of pharmaceutical production in India seems to be stuck in the pre-reform days of autarky, bereft of ambition and oblivious of the global opportunities the sector holds out for India. The drug controller general of India has reportedly admitted that if we followed US standards, we would need to shut down most domestic pharma facilities. It betrays a defeatist mindset and worse. Instead, we surely need world-class quality control in domestic pharma to realise our potential to be the pharmacy of the world. True, the Indian pharma industry does already supply generics to over 200 nations and territories. But the potential upside is simply huge if we follow the highest global standards. The size of the US generics drug market alone is $80 billion, and fast growing.

Also, when it comes to advanced manufacturing capability, pharma is the lone sector where we have something of a toehold. Hence the vital need not to be behind the curve when it comes to its regulation and oversight.

The notion that our norms and regulations need only be good enough to make available affordable medicines is spurious. Rather, we need to go out of our way to create incentives to allocate human and financial resources to shore up quality standards in pharma manufacture and boost exports, leveraging our resource endowment and skill base. And instead of leaving it to the US Food and Drug Administration to routinely find faults with plants here—the latest being Ranbaxy's Toansa facility—our regulatory authorities clearly need to be much more proactive.

It is true that the mandate of the national drugs regulator is more voluntary than statutory; manufacturing compliance and quality assurance is supposed to be the lookout of the concerned state. It points to the pressing need to overhaul and modernise the entire regulatory structure with stepped up resources and capacity building. Without uncompromising standards and norms that are regularly updated, we would stand to greatly forfeit the massive potential of pharma manufacturing for the national good.

Regulatory.