Faster implementation of Rule 101 to accelerate India's healthcare system

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The Indian pharmaceutical industry supplies over half the world's vaccines and are the global leaders in generic drugs. There are several drug companies and manufacturing units that meet this global demand for lifesaving medicines and therapeutics.

While the Indian pharma sector ranks 3rd worldwide by volume of pharma products, in terms of value to the industry, is ranked 14th . To consolidate the value chain and harness the sector's potential to reinforce its prowess globally, boosting innovation and fast-tracking new products into the marketplace is imperative. One way to achieve this is through collaborations and partnerships across the pharma value chain.

There is immense scope for strategic partnerships between the Government, industry stakeholders and the academia, in this space, which will help strengthen the regulatory mechanism in the pharma ecosystem. An example of this partnership is the expedition of not only development, but also the approvals and availability of the COVID-19 vaccines. This will effectively provide thrust to arresting the spread of the virus while highlighting the importance of globally harmonizing patient-centric regulations.

Smooth and streamlined regulatory processes will ensure that patients gain access to newer therapeutic options. It will also facilitate ease of doing business in the sector which will pave the way for a stronger pharma sector that can deliver on vital parameters of patient centricity.

Expediting the entry of new drugs into India will also go a long way to reducing India's drug lag – i.e. the time gap between the launch of new therapeutics in India after they have been rolled out in other global markets such as the US. This drug lag puts Indian patients at a disadvantage as it prevents them from accessing new drugs often for diseases with unmet medical needs. The Indian market for instance, does not get access to new cardiovascular drugs at the same time as patients in developed nations even though the standardized burden of cardiovascular diseases is relatively higher in developing countries.

The New Drug and Clinical Trial Rules 2019 (NDCT 2019) aims to enable more, better and faster drug trials. For example, NDCT 2019 offers specific provisions for expediting drug approvals, thereby ensuring that Indian patients may get early benefits of global advances and cutting-edge products. The Act also specifies certain rules and conditions under which the local clinical trials maybe waived for import of new drugs. Such rules can help address the drug lag in the country.

Rule 101 is key

Here, Rule 101 of the NDCT Act can play a key role in changing the outlook of the pharma marketplace. Rule 101 allows the Drugs Controller General of India (DCGI) to specify certain countries for considering waiver of local clinical trials for approval of new drugs. Notifying a list of countries with well-regulated clinical trial processes and governance mechanisms – for instance, the US, UK, or EU – under Rule 101 is a key step. This notification will enable decisions on waiver of the requirement for local Phase III clinical trials to be taken in a consistent, predictable manner.

In addition to eliminating the delay in regulatory approvals, it will also ensure that Indians get the life-saving advantage of early access to newer treatment options (including vaccines) that have been tested, approved, and are already available in established markets. Rule 101 can yield many benefits, such as ensuring a robust regulation-bound pathway to new launches for the pharmaceutical industry. Notifying the list will help overcome unwarranted delays and inconsistencies in waivers while enhancing the overall ease of doing business in the pharmaceutical sector.

The pandemic has provided ample thrust to every facet of the pharma ecosystem in the country – from boosting innovation and manufacturing to strategic partnerships with global counterparts, ensuring patient centricity. The regulatory landscape has also leveraged the pandemic to make some much necessary overhauls to safeguard the health of the country amidst trying times. The implementation of rules such as Rule 75 and Rule 101 of the New Drug and Clinical Trial Rules (2019) will be pivotal for India in the post-pandemic era. The on-ground execution of such laws will not only consolidate the country's position in the global pharmaceutical ecosystem but will also safeguard patient centricity, which is the need of the hour.

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[1]https://www.ibef.org/industry/pharmaceutical-india.aspx
[2]https://www.ibef.org/industry/pharmaceutical-india.aspx
[3]Drug lag for cardiovascular drug approvals in India compared with the US and EU approvals