The implications of waiving local clinical trials for drugs in India: a double-edged sword?

Rajmohan Seetharaman

Department of Pharmacology, MGM Medical College & Hospital, MGM Institute of Health Sciences (MGMIHS), Nerul, Navi Mumbai, 400706, India

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India's decision to waive local clinical trials for drugs approved in countries like the U.S., U.K., Japan, and the European Union represents a pivotal regulatory shift. While the move aims to expedite access to essential medications and enhance market availability, it raises significant concerns about patient safety, research and development (R&D), and broader healthcare implications.[1]

The decision applies to five categories of drugs, including orphan drugs for rare diseases, gene and cellular therapies, pandemic-related drugs, defense-specific treatments, and drugs with significant therapeutic advancements.[1] The goal is to provide rapid access to life-saving treatments, especially where alternatives are limited. For instance, during the COVID-19 pandemic, remdesivir was fast-tracked globally, highlighting the importance of accelerated drug access.[2,3]

However, waiving local clinical trials presents safety concerns. Trials are essential for assessing how drugs interact with diverse genetic profiles. India's population diversity means bypassing trials could result in unanticipated adverse effects or reduced efficacy.[4,5] Countries like Japan and China mandate local testing or foreign data analysis for ethnic sensitivity, emphasizing the importance of safety through localized validation.[6,7] Japan's cautious approach to genetic diversity in drug metabolism and China's regulatory framework highlight the need for India to consider its own population's unique traits.[8]

Gene and cellular therapies, which manipulate genetic material, carry long-term risks that are not yet fully understood. Similarly, drugs with significant therapeutic advancements need careful scrutiny, as skipping local trials could compromise safety in a genetically diverse population.[9] For example, CAR-T therapies, which modify immune cells, require thorough local testing to account for ethnic variability in genetic responses.[10]

Beyond safety, this policy change could undermine India's R&D ecosystem. Local clinical trials generate invaluable data tailored to India's demographic and environmental conditions. Waiving these trials risks weakening India's pharmaceutical innovation, as companies may lose incentives to conduct localized research. Additionally, it could diminish India's robust research infrastructure, including contract research organizations (CROs), and reduce investments in local drug development.[11,12]

The waiver may disproportionately benefit multinational corporations (MNCs) by allowing faster market entry.[13] While this could enhance access to advanced treatments, it may stifle domestic pharmaceutical companies' innovation and reduce opportunities for localized research. Critics argue that this policy could prioritize commercial interests over public health by enabling MNCs to bypass local safety evaluations.[11,13] Drugs with significant therapeutic advancements present particularly high risks, where the lack of thorough local testing could lead to adverse outcomes.[13]

To mitigate these risks, the government should strengthen post-marketing surveillance for drugs exempt from local trials. Countries like the U.S. and the European Union have robust post-marketing systems, and India could model similar mechanisms to ensure ongoing safety assessments. Additionally, encouraging India's participation in multinational clinical trials, as seen during COVID-19 vaccine research, would ensure global contributions while addressing local needs.[14]

In conclusion, India's waiver of local clinical trials marks a significant regulatory shift. While it could expedite access to innovative treatments, the policy must be implemented carefully to ensure patient safety, safeguard R&D efforts, and balance commercial interests with public health.

Contributors

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Declaration of interests

None declared.

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E-mail address: rajmohan.seetharaman@gmail.com.

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