6. New Drugs Nd Clinical Trail Rules- Governance

Health Ministry eases drug trial norms; cuts licence requirement

The Union Ministry of Health and Family Welfare's notification of the New Drugs and Clinical Trials (Amendment) Rules, 2024 and 2026 represents a major shift toward a "trust-based" regulatory regime. By transitioning from a restrictive licensing model to a notification-based framework, India aims to cement its status as the "Pharmacy of the World" while accelerating the transition from a generic-led to an innovation-led industry.

Rationale Behind the Reforms

India is a global pharmaceutical powerhouse, yet its R&D pace has historically been hindered by red tape.

Global Supplier Status- India accounts for 20% of global generic drug exports by volume.

The "Regulatory Lag- Industry stakeholders have long identified lengthy approval cycles as a deterrent to high-value innovation.

Economic Objective- To increase India's current 8% share in global clinical trials by creating a predictable, fast-tracked environment.

Jan Vishwas Siddhant- The reforms align with the government's principle of de-criminalizing minor offenses and reducing the compliance burden on businesses.

Key Amendments- Detailed Breakdown

The amendments target the two most frequent regulatory interactions- testing licenses and clinical study permissions.

Test License vs. Prior Intimation

For decades, any pharmaceutical R&D required a "Test License" (Form CT-11) from the CDSCO before manufacturing even small quantities for research.

The Shift- The mandatory license for non-commercial manufacture (small quantities for research/analysis) is replaced by an Online Prior Intimation mechanism.

Notify and Proceed- Once an online intimation is submitted and acknowledged, the industry can proceed immediately without waiting for a physical license.

Reduced Timelines- For categories where licenses are still mandatory (e.g., high-risk drugs), the processing time is slashed from 90 days to 45 days.

Risk-Based Exclusions- This "easy route" is not available for high-risk categories to ensure safety-

a. Cytotoxic (anti-cancer) drugs.
b. Narcotic and Psychotropic substances.
c. Sex hormones and certain Biologics (e.g., live microorganisms).

Bioavailability/Bioequivalence (BA/BE) Study Waivers

BA/BE studies are crucial for testing how a generic drug compares to a brand-name original in the human body.

Permission Waiver- Prior approval is no longer needed for low-risk BA/BE studies (specifically single-dose, oral formulations for export purposes in healthy adults).

Self-Regulation- Manufacturers can initiate these studies post-intimation, provided they have approval from a registered Ethics Committee.

Comparison- Old vs. New Regulatory Framework

Feature	Pre-Amendment (NDCT 2019)	Post-Amendment (2024/2026)
Research License	Mandatory "Test License" for all drugs.	Prior Intimation (for non-commercial R&D).
Approval Wait Time	Up to 90 days.	Immediate (post-intimation) or 45 days (for licenses).
BA/BE Study Norms	Prior permission from CDSCO required.	Waiver for specified low-risk studies.

CRO Oversight	Minimal formal registration for all.	Mandatory Registration for all CROs (valid for 5 years).
Digital Integration	Fragmented offline/online processes.	Fully integrated with NSWS and SUGAM portals.

Operational & Digital Enablement

The government is utilizing technology to ensure that "speed" does not come at the cost of "transparency."

National Single Window System (NSWS)- A unified platform for all investor-related approvals.

SUGAM Portal- The CDSCO's dedicated portal for pharmaceutical regulation is being upgraded with new modules for "Prior Intimation."

Clinical Research Organizations (CROs)- For the first time, a clear definition and mandatory registration for CROs have been introduced. They must now maintain records for 5 years and are subject to inspections without prior notice.

Significance of the Amendments

Ease of Doing Business- Removes the "license raj" from the laboratory, allowing researchers to pivot and experiment faster.

Resource Optimization- By automating ~35,000 annual test license applications, the CDSCO can redirect its manpower toward high-priority inspections and safety monitoring.

Global Trust- Aligning with global "best practices" makes India a more reliable destination for multinational pharmaceutical R&D outsourcing.

Challenges and the Way Ahead

While the industry has cheered the move, critics point to potential "blind spots"-

Regulatory Dilution Risk- "Lighter compliance" must not lead to "relaxed safety." Robust post-intimation audits are essential.

Ethical Safeguards- With faster trial initiations, the role of Ethics Committees becomes even more critical in protecting trial participants.

Capacity Building- Regulators need advanced training to transition from a "gatekeeper" role to a "supervisory/monitoring" role using AI and digital data logs.

Source- **https-//www.thehindu.com/sci-tech/health/health-ministry-notifies-amendments-to-new-drugs-and-clinical-trials-rules-2019/article70560009.ece**