# Regulatory Misalignment in Pharma: Fix the System, Not the Industry

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**To ensure that regulatory responsibility is shared transparently and enforced uniformly**

India’s pharmaceutical regulatory framework has long operated through a dual structure, wherein State Food and Drug Administrations (FDAs) are responsible for granting manufacturing licences, while the Central Drugs Standard Control Organisation (CDSCO) exercises oversight on new drugs, including requirements under the New Drugs and Clinical Trials Rules, 2019.

While this shared model is intended to balance decentralised efficiency with central scientific oversight, a structural gap has persisted for decades. In practice, certain pharmaceutical products that qualify as “new drugs” under the 2019 Rules (and previously under Schedule Y) have, at times, received manufacturing licences from State FDAs without prior CDSCO approval, also bypassing clinical trial requirements when applicable.

**Regulatory inconsistency with significant implications**

Pharmaceutical companies, acting in good faith, may obtain licences from State authorities that are fully empowered to grant manufacturing permissions. However, when such products later come under scrutiny for lacking CDSCO approval, the resulting enforcement narrative often places disproportionate accountability on the industry.

If a State FDA grants a licence for a product that legally falls under the “new drug” category requiring CDSCO approval, the primary lapse is institutional, not industrial. The regulatory system must ensure internal alignment before attributing fault externally.

**Illustrative Cases Highlighting Regulatory Misalignment**

A few well recognised instances help illustrate how this regulatory gap manifests in practice. Sodium Hyaluronate 0.3% ophthalmic solutions, used for the management of dry eye disease, have in few cases been licensed at the State level despite representing a higher strength than conventionally approved formulations, thereby potentially qualifying as a “new drug” under the New Drugs and Clinical Trials Rules, 2019.

Similarly, fixed-dose combinations such as Finasteride with Minoxidil for topical use in androgenetic alopecia have appeared in the market through State licensing pathways, even though such combinations typically warrant phase 3 trials if filed before CDSCO.

These examples underscore the need to address systemic inconsistencies at the regulatory interface, rather than attributing isolated liability to industry participants operating within granted permissions. If such cases land in court, who would be held responsible for violating CDSCO framed rules? The wrong applicant or the state regulator is anyone’s guess.

At present, enforcement visibility appears asymmetric. Public advisories and alerts are frequently directed at pharmaceutical companies, while instances of regulatory overreach or misinterpretation at the State level receive limited scrutiny. This risks creating an uneven accountability framework and undermines industry confidence in regulatory predictability.

**Building a Cohesive Approval Framework**

There is a clear need for a formalized mechanism that mandates State FDAs to refer all products falling under the definition of “new drugs” to CDSCO for prior evaluation and approval. Such a provision should not be advisory in nature, but codified within the regulatory framework to eliminate ambiguity.

Key elements of such a reform could include:

- A mandatory referral pathway from State FDAs to CDSCO for all new drug classifications
- A centralized digital tracking system for applications requiring dual oversight
- Mandating an ISI like seal on each pack with “CDSCO Approved new drug” mark on all new drugs
- Clear accountability provisions defining jurisdictional responsibility in case of non-compliant approvals
- Periodic joint audits between central and state regulators to ensure alignment

Encouragingly, CDSCO has already taken steps towards harmonization through dossier-based evaluation guidance and increased regulatory communication. However, without enforceable structural alignment, these efforts may not fully address the root cause of the discrepancy.

**Regulatory Clarity and Patient Safety: Two Goals, One Path**

Patient safety must remain paramount. Equally, regulatory clarity is essential to ensure that compliant pharmaceutical companies are not penalized for operating within permissions granted by competent authorities.

A harmonised regulatory ecosystem delivers multiple benefits:

- Patients receive medicines evaluated under consistent scientific standards
- Healthcare professionals prescribe with greater confidence
- Regulators operate within clearly defined and coordinated roles
- Provides pharma companies with level playing field removing discrimination between law abiding companies and those using regulatory shortcuts
- Industry invests with predictability and accountability

India’s pharmaceutical sector has achieved global credibility through quality and scale. Sustaining this leadership requires regulatory systems that are not only robust, but also internally consistent. The objective is not to dilute oversight, but to ensure that regulatory responsibility is shared transparently and enforced uniformly.

Closing this long-standing gap will strengthen trust across stakeholders and reinforce India’s commitment to a scientifically grounded and accountable pharmaceutical regulatory framework.

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