

## Recent amendments in the Drugs and Clinical Trials Rules

**Prelims:** Current events of national and international importance | Government policies and interventions

### Why in News?

Recently, the Union Health Ministry has notified key amendments to the NDCT Rules, 2019, to promote Ease of Doing Business in the pharmaceutical sector.

- **Aim** - To simplify regulatory processes and reduce approval timelines and to enable faster conduct of clinical research and pharmaceutical development in the country.
- **Nodal ministry** - Union Ministry of Health and Family Welfare.
- **Objective** - To tackle regulatory burden, accelerate drug development and clinical research, and promote ease of doing business while ensuring public health and safety.
- **Implemented by** - **Central Drugs Standard Control Organization (CDSCO)** - Regulates test licences, clinical trials, and Bioavailability/Bioequivalence (BA/BE) studies.
- **National Single Window System (NSWS) and SUGAM Portal** - Enable online submission and monitoring through dedicated modules
- **Key Amendments** - The regulatory reforms introduced through the 2026 amendments to the NDCT Rules, 2019, include

Components	Provisions
Prior-Intimation Mechanism	<ul style="list-style-type: none"> <li>Licensing requirement for non-commercial manufacture replaced with online prior-intimation to CDSCO.</li> <li><b>Exclusion</b> - High-risk drugs (cytotoxic, narcotic, psychotropic) remain under test licence requirement.</li> </ul>
Timeline reduction	<ul style="list-style-type: none"> <li>Drug development timelines reduced by from 90 days.</li> <li>Statutory processing of test licences cut from 90 to 45 days.</li> </ul>

<b>BA/BE Studies</b>	<ul style="list-style-type: none"> <li>• Prior permission waived for specified low-risk Bioavailability/Bioequivalence studies.</li> <li>• Online intimation mechanism introduced.</li> <li>• CDSCO processes ~4,000-4,500 BA/BE applications annually.</li> </ul>
<b>Regulatory Efficiency</b>	<ul style="list-style-type: none"> <li>• Enables optimal utilisation of CDSCO manpower and faster oversight by reducing regulatory burden. <ul style="list-style-type: none"> <li>- CDSCO handles ~30,000-35,000 test licence applications yearly</li> </ul> </li> </ul>

## Reference

[PIB | the New NDCT Rules, 2019](#)

