

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

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

Reference

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

