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	• 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	• Drug development timelines reduced by from 90 days. • Statutory processing of test licences cut from 90 to 45 days.

BA/BE Studies	• 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	• Enables optimal utilisation of CDSCO manpower and faster oversight by reducing regulatory burden. - CDSCO handles ~30,000–35,000 test licence applications yearly

Reference

PIB | the New NDCT Rules, 2019

