Draft rules: antimicrobials to need a central nod as 'new drugs'

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News

The Union Ministry of Health and Family Welfare announced on 19 November 2026 a draft notification amending the New Drugs and Clinical Trials (NDCT) Rules, 2019. 'Antimicrobials' will be added to the definition of 'new drug' in Rule 2(1)(w)(v). If finalised, a firm wishing to make these medicines must first get permission from the Central Licensing Authority (CLA) and only then seek a manufacturing licence from the State Licensing Authority (SLA). The Ministry flagged concern that manufacturing licences were being granted without adequate regulatory scrutiny such as bioavailability/bioequivalence (BA/BE) and stability studies, and said substandard or ineffective antimicrobials help antimicrobial resistance (AMR) spread. The draft, G.S.R. 983(E), is dated 6 November; objections and suggestions may be sent within 30 days of its Gazette publication, it was reported. The Ministry also cited the G20 New Delhi Leaders' Declaration, which stressed a One Health approach.

Key facts for the exam

Point	Details
Ministry	Union Ministry of Health & Family Welfare
Draft	G.S.R. 983(E) dated 6 Nov 2026 (reported); announced 19 Nov
Rules amended	NDCT Rules, 2019 – Rule 2(1)(w)(v)
Change	Antimicrobials treated as 'new drugs'

Point	Details
Licensing order	Central Licensing Authority nod first → then State licence
Reason	Licences without BA/BE & stability studies; poor drugs fuel AMR
Comments	30 days from Gazette publication
AMR toll	4.71 million deaths associated, 1.14 million attributable in 2021 (Lancet)

Background

- Constitution: 'Drugs and poisons' are in the Concurrent List (Entry 19) of the Seventh Schedule, so both the Union and the States can legislate. Under the central Drugs and Cosmetics Act, 1940, new-drug approval, imports and clinical trials are handled by the Drugs Controller General of India (DCGI), who heads the Central Drugs Standard Control Organisation (CDSCO), while State drug-control departments grant manufacturing and sale licences for most drugs. The draft seeks to strengthen central oversight within this dual system.
- NDCT Rules, 2019: these rules govern new drugs, clinical trials, bioavailability/bioequivalence studies and ethics committees. If a drug is a 'new drug', marketing or manufacturing it needs the Central Licensing Authority's permission. A BA/BE study checks whether a generic delivers the same amount of active ingredient into the blood at the same rate as the reference medicine; a stability study confirms that quality lasts until expiry.
- Science: 'antimicrobials' is the umbrella term for medicines against bacteria (antibiotics), viruses, fungi and parasites. Wrong doses, needless use and substandard drugs help microbes resist medicines (AMR). In 2017 WHO grouped antibiotics into three 'AWaRe' categories – Access, Watch and Reserve; 'Reserve' drugs are to be used only when others fail.
- History and economy: Hindustan Antibiotics Ltd, the first public sector undertaking in India's drugs sector, was set up on 10 March 1954 at Pimpri near Pune, marking the country's early step into antibiotic production such as penicillin. Today India is one of the world's big generic-medicine producers, so quality control of antibiotics matters for public health at home and for export credibility. While CDSCO watches drug quality, prices are regulated under the Drugs (Prices Control) Order by the National Pharmaceutical Pricing Authority (NPPA), set up on 29 August 1997.

Tamil Nadu link: In Tamil Nadu, the Tamil Nadu Medical Services Corporation (TNMSC) procures, stores and supplies essential medicines, antibiotics included, to government hospitals – it was incorporated on 1 July 1994 under the Companies Act, 1956 and has functioned since January 1995. If the draft is finalised, Tamil Nadu drug makers too will need central permission before approaching the State Licensing Authority for a licence to make antimicrobials.

Frequently asked questions

What is this news about?

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What are the key facts to remember for the exam?

Ministry: Union Ministry of Health & Family Welfare; Draft: G.S.R. 983(E) dated 6 Nov 2026 (reported); announced 19 Nov; Rules amended: NDCT Rules, 2019 – Rule 2(1)(w)(v); Change: Antimicrobials treated as 'new drugs'.

What is the background to this news?

Constitution: 'Drugs and poisons' are in the Concurrent List (Entry 19) of the Seventh Schedule, so both the Union and the States can legislate.

Practice questions (with answers)

1. Under the draft, antimicrobials will be added to the definition of 'new drug' in which rules?

A) NDCT Rules, 2019

B) Drugs Rules, 1945

C) Medical Devices Rules

D) Cosmetics Rules, 2020

Answer: A – Explanation: New Drugs and Clinical Trials Rules, 2019 – Rule 2(1)(w)(v). A State manufacturing licence only after Central Licensing Authority permission.

2. The Drugs Controller General of India (DCGI), who approves new drugs and clinical trials, heads which body?

A) ICMR

B) FSSAI

C) Pharmacy Council of India

D) CDSCO

Answer: D – Explanation: CDSCO – Central Drugs Standard Control Organisation, under the Drugs and Cosmetics Act, 1940. ICMR does medical research; FSSAI handles food safety.

3. Hindustan Antibiotics Ltd (1954), the first public sector undertaking in India's drugs sector, is located at:

A) Pimpri, Pune

B) Rishikesh

C) Hyderabad

D) Gurugram

Answer: A – Explanation: Pimpri (Pune, Maharashtra) – incorporated on 10 March 1954; a company under the Union Department of Pharmaceuticals.

4. Which body fixes the ceiling prices of scheduled medicines under the Drugs (Prices Control) Order?

A) NITI Aayog

B) CCI

C) NPPA

D) Tariff Commission

Answer: C – Explanation: NPPA – National Pharmaceutical Pricing Authority, set up on 29 Aug 1997; now under the Department of Pharmaceuticals. CCI regulates market competition.

5. In WHO's 'AWaRe' classification of antibiotics, what does the letter 'R' stand for?

A) Restricted

B) Reserve

C) Resistant

D) Regulated

Answer: B – Explanation: Access, Watch, Reserve – introduced in 2017. 'Reserve' antibiotics are last-resort drugs, used only when others fail.

Sources: ThePrint; The Hans India (IANS); The News Mill; WHO; Department of Pharmaceuticals; Department of Pharmaceuticals (NPPA); DGHS (CDSCO); TNMSC. © Shanmugam IAS Academy.