A big step against drug resistance: proposal to bring antimicrobials under central oversight



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The proposals -

The Union Health Ministry has proposed four changes to the New Drugs and Clinical Trials Rules, 2019 and the Drugs Rules, 1945. All drafts are open for public feedback.

1. All antimicrobials as 'new drugs' -

Under the 6 November proposal every antimicrobial medicine will be treated as a 'new drug': manufacturers must first obtain approval from the central drug regulator (CDSCO) before seeking a state manufacturing licence. The ministry has voiced concern that state regulators granted manufacturing licences without adequate testing. The rule applies prospectively; existing licences stay valid.

2. Separate licence for bulk drugs -

A draft notice of 2 November replaces the common wholesale licence for raw drug ingredients (APIs) with a separate licence. Sales must be supervised by a qualified expert and handling of narcotics and psychotropic substances will be tracked. Existing wholesalers have until expiry of their current licence or retention period or 12 months after final publication of the amendment, whichever is later.

3. Mandatory storage and distribution standards -

Good storage and distribution practices developed by the central regulator become mandatory, preserving quality from factory to patient and curbing counterfeiting and illegal diversion.

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4. Relief for medical gases, empty gelatin capsules, disinfectants -

A 6 November draft proposes continuing the existing exemptions for these products, in line with their specific manufacturing processes and February 2026 expert panel recommendations, without lowering quality standards.

Why AMR matters -

Substandard or ineffective antimicrobials drive antimicrobial resistance. The G20 New Delhi Leaders' Declaration called for coordinated human, animal and environmental health action (One Health) against AMR.

Mains practice question

Q1. How far can the proposal to bring antimicrobials under central regulatory oversight address the challenge of antimicrobial resistance (AMR)? Review India's drug-regulation framework. (250 words)

Answer outline

Introduction - the AMR public-health crisis and the four proposals. Body - value of central prior approval; the old centre-state dual-regulation problem; bulk-drug licensing and supply-chain tracking; the One Health approach; challenges: enforcement capacity, burden on small manufacturers, over-the-counter sales. Conclusion - regulation must pair with awareness, diagnostics and stewardship programmes.

FAQ

Q: Will existing licences be cancelled? A: No. The new rule applies to future applications only.

Q: What is AMR? A: When microbes become resistant to medicines, making infections hard to treat.

Sources:

- https://www.livemint.com/science/health/india-curbs-antimicrobial-resistance-tighten-bulk-drug-supply-chains/amp-11795078008198.html
- https://ddnews.gov.in/en/health-ministry-proposes-amendment-to-drug-rules-to-bring-antimicrobials-under-central-regulatory-oversight/
- https://www.pib.gov.in/PressReleasePage.aspx?PRID=2338242&lang=1&reg=48

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