Union Health Ministry Proposes Amendment to New Drugs and Clinical Trials Rules, 2019 to Bring Antimicrobials under Central Regulatory Oversight

Proposed Amendment to NDCT Rules, 2019 Aims to Strengthen Oversight of Antimicrobials and Address AMR

Posted On: 19 NOV 2026 10:31AM by PIB Delhi

Union Ministry of Health and Family Welfare has proposed an amendment to the New Drugs and Clinical Trials Rules, 2019, through a draft Gazette Notification G.S.R. 983 (E) dated 6th November, to include 'antimicrobials' in the definition of 'New Drug' under Rule 2(1)(w)(v).

Antimicrobial resistance (AMR) is a major global public health concern and a priority requiring coordinated action. The G20 New Delhi Leaders' Declaration also underscored the need to address antimicrobial resistance through a One Health approach.

The proposed amendment has been initiated in view of concerns regarding the grant of manufacturing licences for antimicrobial products without adequate regulatory scrutiny, including the requirement for studies such as bioavailability/bioequivalence and stability studies. The absence of such assessments may affect the quality, safety and efficacy of antimicrobial products. Substandard or ineffective antimicrobials can contribute to the development and spread of antimicrobial resistance, posing risks to patient safety.

The proposed amendment seeks to bring antimicrobials within the regulatory framework applicable to new drugs under the New Drugs and Clinical Trials Rules, 2019. Accordingly, manufacturers would be required to obtain permission from the Central Licensing Authority (CLA) before applying for a manufacturing licence from the concerned State Licensing Authority (SLA). This is expected to strengthen central regulatory oversight and help ensure the quality, safety and efficacy of antimicrobial products.

The draft notification has been issued to invite objections and suggestions from stakeholders and members of the public before the proposed amendment is considered for finalisation by the Central Government.

Objections and suggestions, if any, may be submitted to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall–C Wing, First Floor, Kartavya Bhawan-1, New Delhi–110001, or through email at drugsdiv-mohfw[at]gov[dot]in, within 30 days from the date on which copies of the Gazette containing the draft rules are made available to the public.

The draft Gazette notification is available at the following link: https://egazette.gov.in/WriteReadData/2026/278020.pdf

*****

SR

HFW/Amendments to New Drugs and Clinical Trials Rules, 2019 /19 November 2026/3

(Release ID: 2338243) Visitor Counter : 560
Read this release in: Urdu , हिन्दी , Nepali , Marathi , Assamese , Gujarati , Tamil

Share

330 words | 1 min read