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Health Ministry brings antimicrobials under scope of central regulatory oversight

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Proposed amendment aims to strengthen regulatory oversight of antimicrobials and address the problem of AMR



The Ministry of Health and Family Welfare has issued a draft gazette notification proposing amendments to the New Drugs and Clinical Trials Rules, 2019. Under this, 'antimicrobials' (antimicrobial drugs) will be included in the 'new drug' as defined in

Rule 2(1)(w)(v).

Antimicrobial resistance (AMR) is a major concern for global public health and is a priority issue that requires coordinated action to address. The G-20 New Delhi Leaders' Declaration also emphasised the need to tackle the problem of antimicrobial resistance through a 'One Health' approach.

This proposed amendment has been initiated in response to concerns related to the issuance of manufacturing licenses for antimicrobial products without adequate regulatory scrutiny. This includes necessary checks such as bioavailability/bioequivalence and sustainability studies. The absence of such assessments could affect the quality, safety, and efficacy of antimicrobial products. Poor-quality or ineffective antimicrobials can contribute to the development and spread of antimicrobial resistance, posing risks to patient safety.

The proposed amendment aims to bring antimicrobials within the regulatory framework applicable to new drugs under the New Medicines and Clinical Trials Rules, 2019. Accordingly, manufacturers must obtain permission from the Central Licensing Authority (CLA) before applying for a manufacturing license from the respective State Licensing Authority (SLA). This is expected to strengthen regulatory oversight at the central level as well as help ensure the quality, safety, and efficacy of antimicrobial products.

Before finalising the central government's proposed amendments, a draft notification has been issued to invite objections and suggestions from stakeholders and the general public.