Central Oversight of Antimicrobials

Prelims: *Current events of national and international importance | Health*

Why in news?

The Union Health Ministry proposes an amendment to the Drug Rules to bring antimicrobials under central regulatory oversight.

- **Inclusion under 'New Drug' definition** – The proposed amendments to the New Drugs and Clinical Trials Rules, 2019 seek to include 'antimicrobials' in the definition of 'New Drug ', bringing them under stricter regulatory oversight.
- **Aim** – To address the growing threat of Antimicrobial Resistance (AMR), a major global public health concern.
- It aligns with the G20 New Delhi Leaders' Declaration, which emphasised the need to address AMR through a One Health approach.
- **Regulatory concern** – The proposed amendment follows concerns over the grant of manufacturing licences for antimicrobial products without adequate regulatory scrutiny, including assessments such as bioavailability and bioequivalence studies and stability studies.
- The absence of such assessments could compromise the quality, safety and efficacy of antimicrobial products.
- Substandard or ineffective antimicrobials may contribute to the emergence and spread of antimicrobial resistance, posing risks to patient safety.
- **Prior approval needed** – Under the proposed framework, manufacturers would be required to obtain prior permission from the Central Licensing Authority (CLA) before applying to the concerned State Licensing Authority (SLA) for a manufacturing licence.
- The move is aimed at strengthening central regulatory oversight and ensuring that antimicrobial products meet the required standards of quality, safety and efficacy.
- **Dedicated licensing framework** – The proposed amendment seeks to establish a dedicated licensing framework for bulk drugs, enabling more focused regulatory oversight of their wholesale sale and greater accountability in the pharmaceutical supply chain.
- **Covers different drugs** – Under the proposed framework, the licence will cover the categories of bulk drugs handled by wholesalers, including drugs covered under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985.
- **Supervised sale** – The sale of bulk drugs will be carried out under the personal supervision of a competent person, thereby strengthening accountability in their distribution and handling.
- **Impact** – Upon implementation, the proposed amendment will
    - Give better control over the sale of bulk drugs by way of wholesale,

- Strengthen enforcement control in relation to antimicrobial resistance and
- The movement of NDPS drugs and require wholesalers of bulk drugs to obtain a separate license for sale.

References

1. DD News | Health Ministry proposes amendment to drug rules
2. The Hindu | Health Ministry proposes to include antimicrobials in 'New Drug' definition

