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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
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Dated: **21 SEP 2026**

CIRCULAR

Sub: Indiscriminate use of painkillers (NSAIDs), antibiotics and associated risk of Chronic Kidney Disease - Reg.

Import, manufacturing, sale and distribution of drugs are regulated under the provisions of Drugs and Cosmetics Act 1940 and Rules thereunder.

As per the said rules, all drugs including non-steroidal anti-inflammatory drugs (NSAIDs) and antibiotics are required to be sold and distributed in the country on prescription of RMP/ specialist only.

Based on applicability, considering their potential risks various drugs including NSAIDs and antibiotics, are placed under Schedules G, H, H1 and X of the Drugs Rules, 1945 and require appropriate medical supervision. Such drugs are required to bear the prescribed warnings, cautions and conditions of sale in accordance with Rule 97 of the Drugs Rules, 1945.

Most of NSAIDs are included in the Schedule H of Drugs Rules, 1945. Thus, are not to be sold by retail without the prescription of a Registered Medical Practitioner as is required in Rule 97 of Drugs Rule, 1945.

Similarly, most of the antibiotic drugs are included in the Schedule H1 of Drugs Rules. Thus, are required to be labelled with following words:

- It is dangerous to take this preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner.

In view of the above, it is mandatory to ensure that, these drug shall only be used when clinically indicated, in the appropriate dose and for the appropriate duration, and under the supervision of a Registered Medical Practitioner.

Accordingly, all concerned stakeholders, including general public, healthcare professionals, pharmacists, retailers, wholesalers, hospitals and other healthcare institutions, are advised/directed, as applicable, to ensure the following:

A. General Public

- I. NSAIDs/painkillers and antibiotics should not be taken indiscriminately, repeatedly or for prolonged periods without medical advice.
- II. Antibiotics should not be used for self-medication or for conditions where

antibiotic treatment is not clinically indicated, such as most uncomplicated viral infections.

- III. Antibiotics prescribed by a healthcare professional should be taken strictly as advised and should not be shared with other persons or used from leftover medicines.
- IV. Individuals, particularly those with pre-existing kidney disease or other risk factors for renal impairment, should inform their healthcare professional before using NSAIDs.
- V. The public is advised to seek medical advice where pain, fever or other symptoms persist or recur rather than repeatedly using painkillers or antibiotics on their own.

B. Healthcare Professionals

- I. NSAIDs and antibiotics should be prescribed only when clinically indicated, after considering the patient's clinical condition, age, co-morbidities, concomitant medicines and relevant risk factors.
- II. The lowest effective dose for the shortest appropriate duration should be considered when prescribing NSAIDs, particularly in patients at increased risk of renal impairment.
- III. Appropriate precautions should be taken in patients with renal impairment, dehydration, cardiovascular disease or other conditions that may increase the risk associated with NSAID use.
- IV. Antibiotics should be prescribed judiciously and in accordance with applicable antimicrobial stewardship principles, taking into consideration the likely causative organism, site and severity of infection and, wherever appropriate, relevant microbiological investigations and local susceptibility patterns.
- V. Unnecessary combination therapy, inappropriate antibiotic selection, incorrect dosing and unnecessarily prolonged duration of antibiotic treatment should be avoided.

C. Pharmacists, Retailers and Distributors

- I. The statutory requirements relating to the sale and distribution of Schedule H, H1 and other prescription drugs shall be strictly complied with.
- II. Schedule H/H1 drugs shall not be sold at retail except in accordance with the applicable provisions of the Drugs Rules, 1945.
- III. Pharmacists and retailers shall not encourage or facilitate self-medication with antibiotics or prescription-only NSAIDs.
- IV. The prescribed warnings and conditions of sale appearing on the labels of such medicines shall be duly observed.

D. Hospitals and Healthcare Institutions

Hospitals and healthcare institutions are advised to strengthen systems for rational prescribing and monitoring of NSAIDs and antibiotics and to promote antimicrobial stewardship, prescription review and appropriate patient counselling.

- E. State/UT Drugs Control Authorities are requested to create awareness

among healthcare professionals, pharmacists, retailers and the general public regarding the risks associated with indiscriminate use of NSAIDs and antibiotics and to ensure compliance with the applicable provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.

In view of above, all concerned are advised to take necessary steps to promote rational, safe and responsible use of NSAIDs and antibiotics and to prevent avoidable adverse drug reactions, renal complications and antimicrobial resistance.


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Copy for information to:

1. PPS to DGHS
2. PS to JS, MoHFW, New Delhi
3. Deputy Director, NCD-II Division, MoHFW
4. CDSCO website