GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 1191
TO BE ANSWERED ON 06TH FEBRUARY, 2026

NIMESULIDE DOSAGE BAN

1191. DR. AMOL RAMSING KOLHE:
PROF. VARSHA EKNATH GAIKWAD:
SHRI MOHITE PATIL DHAIRYASHEEL RAJSINH:
SHRI SANJAY DINA PATIL:
SMT. SUPRIYA SULE:
SHRI BHASKAR MURLIDHAR BHAGARE:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government has banned the manufacture, sale and distribution of oral formulations of Nimesulide above 100 mg for human use in the country due to serious safety concerns, including liver toxicity and if so, the details thereof;

(b) whether this ban is being effectively enforced in Maharashtra and if so, the details thereof;

(c) the scientific studies, pharmacovigilance data and expert recommendations relied upon for this decision, including inputs from the Indian Council of Medical Research and the Drugs Technical Advisory Board;

(d) whether cases of adverse drug reactions, hospitalisation or liver damage linked to high dosage nimesulide have been reported in Maharashtra during the last five years, district-wise and the regulatory action taken thereon; and

(e) whether any advisories, monitoring drives or awareness programmes have been undertaken in Maharashtra for doctors, chemists and the public on safer alternatives and rational use of analgesics and if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAP RAO JADHAV)

(a) to (e): Based on the examination of the report of the Indian Council of Medical Research (ICMR) by the Drugs Technical Advisory Board (DTAB) and its recommendations made in the meeting held on 24.04.2025, the Central Government, has prohibited the manufacture, sale and distribution of all oral formulations containing Nimesulide above 100 mg in immediate-release dosage form vide Gazette Notification S.O. 6091(E) dated

29.12.2025, as such formulations are likely to involve risk to human beings and safer therapeutic alternatives are available. Further, vide G.S.R. 82(E) dated 10.02.2011, the Central government had already prohibited the manufacture, sale and distribution of Nimesulide formulations for human use in children below 12 years of age. These notifications are applicable throughout the country.

The manufacture, sale and distribution of prohibited or banned drugs is a punishable offence under Section 18 of the Drugs and Cosmetics Act, 1940, and the concerned licensing authorities are empowered to take appropriate regulatory action in this regard.

The Indian Pharmacopoeia Commission (IPC) as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) collates and analyses, Individual Case Safety Reports (ICSRs) related to adverse drug reactions. As per the reporting mechanism of IPC for suspected adverse drug reactions (ADRs), during the last five years, one case of ADR associated with high-dose Nimesulide (>100 mg) requiring hospitalisation was reported from Mumbai district of Maharashtra.

Further, the Indian Pharmacopoeia Commission has undertaken multiple awareness and risk-communication initiatives to strengthen the safe use of Nimesulide. These include circulation of safety advisories and awareness posters emphasising the prohibition of Nimesulide use in children below 12 years of age to Adverse Drug Reaction Monitoring Centres (AMCs) and Marketing Authorisation Holders (MAHs). Dissemination has also been carried out through PvPI social media platforms and information hosted on the official website of the Indian Pharmacopoeia Commission (www.ipc.gov.in).

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