

BDMAI/NDPS/DOP/2026

13th January 2026

Mr. Ajay Kumar
Section Officer (Policy)
Department of Pharmaceuticals
Government of India
New Delhi

Dear Sir

Sub: Scheduling of drugs or chemicals under NDPS

Ref: Your mail dated 6th January 2026

With reference to the above mail, we wish to inform that we have circulated the proposed exercise by the department for inclusion of certain chemicals / drugs under NDPS. Many of our members responded objecting to inclusion of the following products under NDPS:

- A) Benzimidazoles and Nitrobenzimidazoles
- B) Tapentadol

Benzimidazoles & Nitrobenzimidazoles:

It may be noted that the above chemicals are key starting material for many commonly used drugs like:

- a) Gastrointestinal drugs – Omeprazole, Esomeprazole
- b) Anthelmintics: Extremely common for treating parasitic worms (nematodes, flukes) in humans and animals (e.g., albendazole, fenbendazole, mebendazole).
- c) Antifungal: Treating fungal infections.
- d) Antiviral & Anticancer: Research shows potential against viruses (like HIV) and various cancers, including breast and prostate cancers.
- e) Antihistamines: Some derivatives act as antihistamines (e.g., bilastine).

If the above KSMs are placed under NDPS, it will have a serious cascading effect on the many life saving drugs. Hence, we strongly recommend not to include these KSMs under NDPS.

Tapentadol:

Many of our members manufacture and supply this drug to various countries, including regulated markets like EU, and also to domestic markets. As per the feedback received from the members, we strongly recommend not to include this product under NDPS, on the following grounds:

- a) The NDPS Act is intended for substances with high abuse potential, strong euphoric reinforcement and significant risk of addiction and diversion. Tapentadol does not meet these criteria when evaluated against internationally accepted pharmacological and epidemiological standards

- b) Tapentadol is a centrally acting analgesic with a dual mechanism - Weak μ -opioid receptor agonism and Noradrenaline reuptake inhibition - This mechanism results in effective analgesia at significantly lower opioid receptor occupancy than classical opioids such as morphine, oxycodone, or fentanyl. Treating Tapentadol as equivalent to strong opioids ignores its distinct pharmacology and violates the principle of risk-proportionate regulation.
- c) Global clinical and post-marketing surveillance data consistently show that Tapentadol has Lower euphoric effect, lower "drug liking" scores, lower rates of misuse and diversion, reduced withdrawal severity. These characteristics are precisely why Tapentadol is preferred in chronic pain, neuropathic pain, and elderly patients, where abuse liability must be minimized.
- d) Including Tapentadol in NDPS would distort critical distinctions between high-risk narcotics and safer opioid-sparing therapies, undermining rational drug scheduling.
- e) Including Tapentadol under NDPS will create procedural barriers for hospitals and physicians, reduce availability in tier-2 and tier-3 cities, discourage prescribing even for genuine indications, push clinicians toward less effective or more dangerous alternatives, including higher-dose opioids or uncontrolled NSAID use
- f) Blanket inclusion of this drug under NDPS would punishes legitimate patients and compliant manufacturers, while historically failing to eliminate illicit misuse. Any instances of misuse may be best addressed through prescription monitoring, making Pharmacist accountable, through medical education and targeted enforcement against illegal diversion
- g) Tapentadol is a critical molecule for India's pharmaceutical ecosystem, including API manufacturing and regulated exports. NDPS inclusion would increase compliance burden disproportionately, disrupt domestic supply chains, reduce India's competitiveness in regulated markets and create artificial shortages without reducing abuse

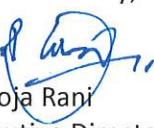
We also enclose herewith information from some of the manufacturers, who are legally manufacturing and supplying to domestic as well as international markets.

In view of the above, we request you to exclude inclusion of Benzimidazoles and Nitrobenzimidazoles & Tapentadol under NDPS and retain them under existing prescription drug regulatory mechanism.

As regards to other products mentioned in the above mail, we are collecting data from our members and will submit the same in a couple of days for your consideration.

Thanking you,

Yours sincerely,


M Roja Rani
Executive Director

