

Date: 1<sup>st</sup> September 2025

To,  
Sri Dharmendra Kumar Yadav,  
Under Secretary to the Government of India  
Department of Pharmaceuticals,  
Government of India

**Sub: OM dated 26<sup>th</sup> of August 2025 No31026/31/2024-Policy. Dept of Pharmaceuticals on Inclusion of Non-Scheduled Precursor Chemicals under Schedule-A of Regulation of Controlled Substances Order of NDPS Act, 1985.**

Dear Sir,

Further to the review of the attached Office memorandum and the impact of inclusion of a widely used chemical - **Mono Methyl Amine (MMA)** and a research chemical **2-Bromo-4-Methylpropionophenone** under Schedule-A of the Regulation of Controlled Substances (RCS) Order, NDPS Act, 1985, we would like to provide some insights into how this inclusion could potentially impact manufacturing and trade.

Firstly, MMA is extensively used in various industries, such as pharmaceuticals, agrochemicals, dyes and textiles, solvents, polymers/resins and water treatment. Introducing stringent regulations by including these chemicals under Schedule-A could create significant disruptions in manufacturing and supply chain, leading to availability of these chemicals, increased costs and delays in production processes. Consequently, this may hinder the growth and competitiveness of businesses relying on manufacturing and use of these chemicals.

Moreover, the additional compliance requirements and bureaucratic procedures under Schedule-A for registration with Narcotics Control Bureau (NCB), maintaining daily records, filing quarterly returns to NCB, transport, selling, destruction, import and export regulations might deter large, small and medium-sized enterprises (SMEs & MSMEs) from manufacturing and dealing with these chemicals. Even large chemical and MSMEs often lack the resources and expertise to navigate complex regulatory frameworks such as RCS Order 2013, and the inclusion of these chemicals could impose an undue burden on these businesses, potentially stifling production, supply chain, innovation and economic growth, as any violation including inadvertent administrative lapses invokes stringent penal provisions of imprisonment for upto 10 years, as per Section 25-A of the NDPS Act, 1985.

Furthermore, these chemicals are not listed in either **Table I or Table II of the 1988 Convention**. However, the International Narcotics Control Board (INCB) has identified it as a **“non-scheduled substance of concern”** and encourages **“voluntary monitoring”** and many national authorities (EU Member States, the U.S., Japan, etc.) treat it as a watched precursor in practice, subject to enhanced scrutiny at customs. The global trade of these chemicals could be adversely affected if brought under controls in India. Export and import activities may face additional hurdles, such as obtaining NOCs from Central Bureau of Narcotics (CBN) and meeting specific regulatory compliances. This could result in

reduced international competitiveness and India losing trade vis-a-vis countries that do not impose similar restrictions.

In light of these considerations, it is crucial to carefully evaluate the potential consequences of economic implications and trade dynamics in including these two chemicals under Schedule-A. It is pertinent to state that we need to ensure the safety and security of potential misuse of these chemicals but it is of utmost importance, that a balanced approach is considered which does not impact trade of such widely used chemicals. It our recommendation that these chemicals are **NOT** brought within the purview of Schedule - A substances of the RCS Order, 2013 and alternate mechanisms are evaluated to control the clandestine manufacture of illicit substances.

Please let us know if you need any further information or assistance.

Questionnaire duly filled in is enclosed for your ready reference

Best regards,

**For Bulk Drug Manufacturers Association (India)**

  
RK Agrawal  
National President