BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA

BDMAI/AP/DCA/2026

30th June 2026

Sri Satya Kumar Yadav
Hon'ble Minister of Health, Family Welfare & Medical Education
State Government of Andhra Pradesh
Room No-211, First Floor, Building No-5
Amaravati. Andhra Pradesh

Sub: Representation regarding delays in grant of licences and statutory approvals by the Drug Control Administration, Andhra Pradesh – Request for administrative reforms to facilitate Ease of Doing Business

Respected Sir,

Greetings from the Bulk Drug Manufacturers Association of India (BDMAI).

On behalf of the Bulk Drug Manufacturers Association of India (BDMAI), we respectfully submit this representation seeking your kind intervention in addressing certain genuine and pressing concerns being faced by pharmaceutical manufacturers and exporters operating in the State of Andhra Pradesh.

The pharmaceutical industry has been one of the strongest pillars of Andhra Pradesh's industrial ecosystem, making a significant contribution to employment generation, exports, state revenues, healthcare, and the growth of several ancillary industries. Timely regulatory approvals are essential for sustaining this momentum and for maintaining the State's reputation as a preferred destination for pharmaceutical manufacturing and investment.

Over the past several months, a large number of our member companies have approached the Association regarding inordinate delays in the grant of manufacturing licences, WHO-GMP Certificates, Certificates of Pharmaceutical Product (CoPP), and other statutory approvals by the Drug Control Administration (DCA), Andhra Pradesh. Because of which the member have lost Export orders thus resulting in financial losses and reputation in the international markets.

The primary reasons behind these issues is that, even after submission of complete applications along with all prescribed documents, applicants often receive neither any communication regarding the status of their applications nor deficiency letters within a reasonable time. Consequently, applications remain pending for prolonged periods, creating uncertainty and adversely affecting business operations.

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It is further understood that a substantial number of applications remain pending at the office of the Director General, Drug Control Administration, for final approval. Despite completion of technical scrutiny and compliance verification by the competent officers at various levels, the files continue to await final clearance for extended periods, resulting in avoidable delays in the issuance of licences and statutory approvals.

We respectfully submit that the involvement of the Director General in the application approval process was originally introduced with a constructive objective—to eliminate delays occurring at intermediate levels where applications were previously pending for several months. The intention was to strengthen supervisory oversight, monitor the movement of applications at every stage, ensure accountability among officers, and facilitate faster disposal of applications.

However, in practice, the additional layer of approval at the Director General level has inadvertently become a major procedural bottleneck. As a large number of applications accumulate for final clearance, the overall processing time has increased considerably, defeating the very objective of expediting regulatory approvals.

Our member companies have also pointed out that frequent transfers of Directors General have disrupted continuity in decision-making and monitoring, further aggravating the situation. Several manufacturers have reported losing confirmed domestic and international orders due to the non-availability of licences and approvals within the required timelines. These delays have resulted not only in substantial financial losses but also in reputational damage with overseas customers, thereby affecting the competitiveness of Andhra Pradesh's pharmaceutical industry.

The pharmaceutical sector is one of the most valuable contributors to the State's economy. It generates substantial GST revenues, attracts significant domestic and foreign investments, creates large-scale employment opportunities, and contributes immensely to India's pharmaceutical exports. Ensuring a transparent, efficient, and time-bound regulatory framework is therefore crucial for strengthening investor confidence and promoting the Government's vision of **Ease of Doing Business**.

Timely issuance of statutory licences and approvals will not only support the expansion of existing pharmaceutical industries but will also encourage new investments in Andhra Pradesh, thereby contributing significantly to the State's long-term industrial development and economic growth.

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In view of the above, we most respectfully submit the following suggestions for your kind consideration:

a) The Director General, Drug Control Administration, may primarily be entrusted with overall administrative leadership, policy implementation, supervision, monitoring, and ensuring strict adherence to the statutory timelines prescribed under the Drugs and Cosmetics Act, 1940, the Rules framed thereunder, and relevant Government notifications.

b) The statutory authority for issuance of manufacturing licences, test licences, WHO-GMP Certificates, Certificates of Pharmaceutical Product (CoPP), and other regulatory approvals may be vested with the Director, Drug Control Administration, who is the technically qualified and designated licensing authority under the provisions of the Drugs and Cosmetics Act and Rules. This would eliminate procedural congestion while retaining effective administrative oversight by the Director General.

We respectfully submit that a similar administrative reforms have been implemented by the Drug Control Administration of various states such as Gujarat, Maharashtra and Telangana wherein the Director General has delegated licensing powers to the Director Licensing authority, thereby facilitating faster disposal of applications without compromising regulatory oversight.

We firmly believe that adopting a similar mechanism in Andhra Pradesh would significantly streamline regulatory processes, reduce approval timelines, improve administrative efficiency, and create a more industry-friendly regulatory environment. Such a progressive initiative would greatly strengthen the confidence of pharmaceutical manufacturers and investors while reinforcing Andhra Pradesh's position as one of India's leading pharmaceutical manufacturing destinations.

We are confident that, under your dynamic leadership, this matter will receive favourable consideration. A timely intervention in this regard will provide immense relief to the pharmaceutical industry and will make a lasting contribution towards the industrial growth, export competitiveness, and economic development of Andhra Pradesh.

We shall be grateful for your kind consideration and favourable action.

Yours sincerely,

Ch. A P Rameswara Rao
National President

Copy to:
a) The Principal Secretary, Dept. of Health, Medical & Family Welfare, Andhra Pradesh
b) Drug Control General India, CDSCO, New Delhi
c) Director General, Drug Control Administration, Andhra Pradesh
d) Director, Drug Control Administration, Andhra Pradesh