

BDMAI/APPCB/2026

11th May 2026

Dr P. Krishnaiah, I.A.S(Retd.)
Chairman
Andhra Pradesh Pollution Control Board
Paryavaran Bhavan,
APIIC Colony Road, Gurunanak Colony,
Autonagar, Vijayawada- 520007.

Dear Sir,

Sub: Representation about some Industry concerns related to CTO/CFOs & Waste Management Facilities in Andhra Pradesh

Greetings from Bulk Drug Manufacturers Association of India!

We would like to bring some of the issues of member industries to your kind notice:

Product Mix:

Bulk Drug industries are allowed to change their product mix (change / increase / decrease number of products) provided there is no change in the total production capacity and there is no increase in the Pollution Load as allowed in the EC obtained by the manufacturer. Further currently Drugs and Intermediates are treated separately and it is not permitted to change from Intermediate to Drug products vice versa without obtaining fresh EC.

In this connection, we would like to bring to your notice GO S.O.980 (E) dated 2nd March 2021, OM Dated Dec 17, 2025 and a recent industry interaction with the senior officials of MoEF on 12th March 2026 at Delhi, wherein it was clarified that industries can change/increase or decrease the number of products and also **the total quantity of Products**, provided there is no increase in Pollution Load and the pollution loads are within the limits of approved EC. Further it is also permitted to treat Drugs and Intermediates as one single category and product change within the category is permissible. We enclose herewith a copy of the minutes of 12th March 2026 and other documents, for your reference.

We shall be highly thankful if a Circular is issued from your side to the industry confirming the above clarifications issued by the MoEF.

Amendment to CTO in Case of Product Mix

Subsequent to the recent amendments and clarifications issued by MoEF&CC, there is no requirement for obtaining Environmental Clearance (EC) in the event of any change in product mix. Presently, the industry is required to submit an application through the Parivesh portal along with a "No Increase in Pollution Load" certificate issued by authorized agencies. The application is thereafter forwarded to the concerned Regional Office for processing. Upon payment of the prescribed fee, the applicant is required to approach the State PCB for obtaining Consent for Establishment (CTE) and thereafter Consent for Operation (CTO).

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However, in practice, it takes nearly 4–6 months for the CTE and CTO Committees to examine such applications and issue the amended CTOs.

As your good office would kindly appreciate, a delay of 4–6 months in obtaining CTO approvals is excessively long and is not aligned with the present international market dynamics, which are highly time-sensitive. In many instances, industries are losing valuable export opportunities and customers due to non-availability of CTO approvals within the required timelines.

In view of the above genuine difficulties being faced by the industry, we humbly request your kind consideration of the following suggestions:

1. Since there is no change to the establishment in cases involving only change in product mix, the requirement for obtaining CTE may kindly be exempted.
2. Existing CTOs may be permitted to be amended directly in cases involving change in product mix.
3. The entire process for obtaining amendment to the existing CTO may kindly be made completely online with clearly defined timelines for disposal and issuance of amended CTOs.
4. A separate and rationalized fee structure may kindly be prescribed for applications relating to change in product mix.

Your kind consideration of the above request would greatly facilitate smooth and efficient operations of the pharmaceutical industry and enhance its ability to respond promptly to changing market requirements.

Escalated costs for Waste Disposal:

Recently, the costs of hazardous waste disposal being charged to pharmaceutical units in Andhra Pradesh have been increased abnormally by Re Sustainability Limited. The reason cited by the agency is that the existing waste disposal facility has reached its full capacity and that approval for allotment of additional land is still pending. Consequently, they are transporting the hazardous waste generated by pharma units in Visakhapatnam and Srikakulam districts to their other facility located in Nellore, thereby incurring additional transportation costs.

At present, the pharmaceutical industry is already under severe financial stress due to steep increases in the prices of raw materials arising out of the ongoing geopolitical situation in West Asia. In this difficult scenario, the additional burden being passed on by Re Sustainability Limited towards transportation and disposal charges is further aggravating the situation and adversely affecting the viability of the industry, particularly MSME units.

We sincerely request your good offices to kindly look into the abnormal escalation in hazardous waste disposal charges being levied by Re Sustainability Limited and take suitable measures to regulate and rationalize the same in the larger interest of the pharmaceutical industry in the State.

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Renewal Fee for CTOs:

We would like to bring to your notice that in Andhra Pradesh, the renewal fee for Consent to Operate (CTO) is being collected upfront for the entire validity period of five years. However, in Telangana, the renewal fee is being collected on a yearly basis during the first quarter of every financial year, based on the turnover reflected in the Balance Sheet or Chartered Accountant's Certificate.

In this regard, we request that a similar system of annual payment of CTO renewal fee may kindly be permitted in Andhra Pradesh as well. Such a provision would significantly ease the financial burden on industries, particularly small and medium-scale enterprises, by avoiding the requirement of making a large lump-sum payment for the entire five-year period at one time.

Request for Appointment:

Our Executive Committee members would also like to meet you and the senior officials concerned to explain the issues in detail and discuss possible solutions. We therefore request you to kindly grant us an appointment at an early convenient date.

Thanking you and looking forward to your response

With regards

For Bulk Drug Manufacturers Association



Ch A P Rameswara Rao
National President

Copy to: Sri S. Sri Saravanan, IFS, Member Secretary
Sri M Rajashekar, Chief Environmental Engineer