IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION NO. 10602 OF 2025

National Pharmaceuticals Through its Director
Mrs Nutan Tiwari, G-18/1, M.I.D.C., Tarapur,
Boisar, District Palghar, 401506. ..Petitioner

Versus

1. Joint Commissioner (K.D.)
Food and Drug Administration, M.S.,
1st Floor, Vardan (MIDC) Building,
Old Passport Office, Wagale Estate,
Road No. 16, Thane (West) – 400 604.

2. The State of Maharashtra,
through the Government Pleader,
Minister of Food and Drug Administration
Mantralaya, Mumbai 400 032

3. Deputy Drug Controller (India),
CDSCO (West Zone),
4th Floor, Zonal FDA Bhavan, GMSD compound
Bellasis Road, Mumbai Central,
Mumbai 400 008. …Respondents

WITH

WRIT PETITION NO. 10603 OF 2025

AVEO Pharmaceuticals Pvt Ltd,
Through its Director- Vinod Kumar Sharma,
Plot No. C/13, M.I.D.C., Tarapur, Boisar,
District Palghar – 401506. ..Petitioner

Versus

1. Joint Commissioner (K.D.)
Food and Drug Administration, M.S.,
1st Floor, Vardan (MIDC) Building,
Old Passport Office, Wagale Estate,
Road No. 16, Thane (West) – 400 604.

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Bellasis Road, Mumbai Central,
Mumbai 400 008. …Respondents

Mr. Amir Arsiwala, with Omprakash Jha, Kalpesh Ulhas Patil & Shraddha Prakash Gajbhiv, for the Petitioner in Writ Petition NO. 10602 of 2025 and Writ Petition No. 10603 of 2025.
Mrs. Vaishali Nimbalkar, AGP, for Respondent No.2-State in WP/10602 of 2025.
Mrs. M.S. Srivastav, AGP, for Respondent No.-2-State in WP/10603/2025.
Mr. D.P. Singh, for Respondent No.3 in WP/10602/2025 and WP/10603/2025.

CORAM: N. J. JAMADAR, J.
RESERVED ON : 26th AUGUST 2025
PRONOUNCED ON : 22nd SEPTEMBER 2025

JUDGMENT:

1. Rule. Rule made returnable forthwith, and, with the consent of the learned Counsel for the parties, heard finally.

2. As both the Petitions arise out of, by and large, similar set of facts, the Petitions were heard together and are being decided by this common judgment.

3. These Petitions assail the legality, propriety and correctness of the orders dated 10th July 2025 passed by the Minister, Department of Food and Drugs, Government of Maharashtra, (R2) in Appeal Nos. 490 of 2025 and 579 of 2025, whereby the Appeals preferred by the Petitioners, in the respective Petitions, against the orders passed by the Joint Commissioner and Licencing Authority, Food and Drugs Administration (R1), directing the Petitioners to completely stop the production of the medicines, came to be dismissed.

4. For the sake of convenience and clarity, the facts in Writ Petition No. 10602 of 2025, are noted in a little detail; followed by the facts in Writ Petition No. 10603 of 2025, in brief.

5. **FACTS IN WRIT PETITION NO. 10602 OF 2025:**

5.1 M/s National Pharmaceuticals, the Petitioner, is a Company incorporated under the Companies Act, 1956. The Petitioner claims to be a reputed pharmaceuticals manufacturing company. The Petitioner holds valid license under the Drugs and Cosmetics Act, 1940 ("the Act, 1940) and the Drugs and Cosmetics Rules 1945 ("the Rules, 1945). The Petitioner has its manufacturing facility at G-18/1, M.I.D.C., Tarapur, Boisar. It employs over 170

workers. The Petitioner claims to have been exporting over 400 products to various countries adhering to the Good Manufacturing Practices (GMP) and national/international standards.

5.2 On 21st February 2025 a Circular was issued by the Government of India, Directorate General of Health Services, directing immediate withdrawal of the permission to manufacture all combinations of Tapentadol and Carisoprodol.

5.3 In deference to the aforesaid directive, the Petitioner surrendered its product license on 23rd February 2025 and the same was approved by R1 on 24th February 2025.

5.4 A joint inspection was conducted by the officials from Central Drugs Standard control Organization (CDSCO) (R3) and the State Food and Drug Administration (FDA) in the manufacturing unit of the Petitioner on 25th February 2025.

5.5 A notice dated 26th February 2025 was issued to the Petitioner under Section 22(1)(cca) read with Section 18-B of the Act, 1940, to produce documents relating to the manufacture for sale of drugs manufactured under export NOCs issued by CDSCO, West Zone Office and FDA.

5.6 Simultaneously by order dated 26th February, 2025, without providing any opportunity of hearing the Respondent No.1

directed the Petitioner to stop the manufacturing of all the products which mandated the cessation of production.

5.7 Subsequently, a show cause notice was issued to the Petitioner on 27th February 2025 under Rule 85(2) of the Rules 1945 for alleged contravention of the provisions of Act of 1940 and the Rules thereunder and for failure to achieve and follow the requirements of the Good Manufacturing Practices and Good Laboratory Practices.

5.8 A compliance report of Corrective Actions and Preventive Actions (CAPA) was submitted by the Petitioner on 3rd March 2025. A reply to the show cause notice dated 27th February 2025 was also submitted.

5.9 As the permission to resume the production was not granted despite all the compliances, the Petitioner preferred an Appeal before the State Government (R2) against the order directing the Petitioner to stop production of all the products.

5.10 By the impugned order dated 10th July 2025, the Minister, Food & Drug Department, dismissed the Appeal without evaluating the legality and correctness of the order passed by the Respondent No.1; which was in clear breach of the statutory requirements.

6. WRIT PETITION NO. 10603 OF 2025:

6.1 The Petitioner is also a pharmaceutical manufacturing company incorporated under the Companies Act 1956. Pursuant to the circular issued by the Directorate General of Health Services, CDSCO, Government of India, directing the immediate withdrawal of the permission to manufacture all combinations of Tapentadol and Carisoprodol, the Petitioner surrendered the license to produce the aforesaid products on 23rd February 2025, and the same was approved by Respondent No.1 on 24th February 2025.

6.2 In the meanwhile, on 21st and 22nd February 2025, a joint inspection was conducted by the officials from Central Drugs Standard control Organization (CDSCO) (R3) and the FDA, State of Maharashtra (R1).

6.3 A notice dated 22nd February 2025, under Section 22(1) (cca) read with Section 18-B of the Act, 1940, was issued to the Petitioner, to produce the documents relating to the manufacture for sale of drugs manufactured under export NOCs issued by CDSCO (R3) and the FDA, Maharashtra.

6.4 Simultaneously, without providing any opportunity of hearing, the Petitioner was directed to stop the manufacture of all the products which mandated the cessation of production.

6.5 The Petitioner claimed to have submitted reply to the show cause notice and compliance report of CAPA. Yet, the permission to stop the production was not revoked.

6.6 The Petitioner thus preferred an Appeal before the State Government (R2). By the impugned order the Appeal was dismissed by the Minister, Food and Drugs Department.

7. Being aggrieved the Petitioners have invoked the writ jurisdiction.

8. As the action was initiated pursuant to the joint inspection conducted by the officials from CDSCO and the State FDA, CDSCO (R3) came to be implemented as a party-Respondent to these Petitions.

9. An Affidavit in Reply is filed on behalf of the Respondent No.3. The substance of resistance put-forth by the Respondent No.3 is that based on the information received and the article published by BBC that, the combination of Tapentadol and Carisoprodol has significant abuse potential and the said combination was being exported to West African countries from India, the Respondent No.3 had directed withdrawal of the permission for manufacture of all combinations of Tapentadol and Carisoprodol considering their potential drug abuse and harmful impact on the population. Under the said Circular, the Respondent No.3 has only withdrawn the export NOCs. The said directive was not manufacturer specific.

10. With regard to the joint inspection conducted at the manufacturing facilities of the Petitioners, the Respondent No. 3(R3), contends that significant discrepancies and deficiencies were found in the said joint inspection and the Petitioners have failed to comply with the observations reported in the joint investigation report and compliance verification.

11. In the wake of the aforesaid pleadings and material, I have heard Mr. Amir Arsiwala, the learned Counsel for the Petitioners, Mrs. Vaishali Nimbalkar, the learned AGP for the Respondent No.2-State in Writ Petition No. 10602 of 2025, Mrs. M.S. Srivastav, the learned AGP, for the Respondent No.2-State in Writ Petition No. 10603 of 2025, and Mr. D.P. Singh, the learned Counsel for the Respondent No.3, in both the Petitions. With the assistance of the learned Counsel for the parties, I have perused the material on record.

12. Mr. Arsiwala, the learned Counsel for the Petitioners, submitted that the impugned orders of stop production are not only in breach of the principles of natural justice but in flagrant violation of the express statutory provisions. Mr. Arsiwala laid emphasis on the fact that the stop production orders were passed by the Respondent No.1 on the very day the Petitioners were called upon to furnish the information with regard to the inspection conducted at the manufacturing units of the

Petitioners, purportedly under Section 22(1)(cca) read with Section 18-B of the Act, 1940.

13. Mr. Arsiwala submitted that on 22nd February 2025 the order of stop production was passed by the Respondent No.1 in Writ Petition No. 10603 of 2025. Whereas the notice to show cause purportedly under Rule 85(2) of the Rules, 1945 was issued two days latter on 24th February 2025. By the said notice the Petitioner in Writ Petition No. 10603 of 2025 was called upon show cause as to why an order to cancel manufacturing license or suspend the same for a suitable period or any other legal action be not initiated against the Petitioner.

14. In Writ Petition No. 10602 of 2025, the stop production order was issued on 26th February 2025 based on inspection of the manufacturing unit on 25th February 2025 and the show cause notice under Rule 85(2) of the Rules, 1945 was issued on 27th February 2025.

15. Mr. Arsiwala would thus urge that, if on the basis of the show cause notice to cancel or suspend the manufacturing licences; to which the Reply is given by the Petitioners, any purported order is passed by the Competent Authority, the Petitioner would work out their remedies. However, the direction to stop production without complying with the mandate of Rule 85 to give an opportunity to show cause, was clearly in violation of the statutory requirements. Therefore, the impugned orders

to stop production passed by the Respondent No.1 and affirmed by the Respondent No.2, in Appeal, deserve to be quashed and set aside.

16. To buttress the aforesaid submissions, Mr. Arsiwala placed reliance on the judgment of the Supreme Court in the case of **Nawabkhan Abbaskhan Vs The State of Gujarat,**[1] a decision of the Rajasthan High Court in the case of **Santokba−The Pharmacy−OPD (M/s.), (A Unit of Tara Medicose Pvt Ltd)**[2] and a decision of the Madras High Court in **M/s Intermed Vs The Director of Drugs Control & Licensing Authority & Ors.**[3]

17. In opposition to this, the learned AGP for the Respondent Nos. 1 and 2-State and Mr. D.P. Singh, the learned Counsel for the Respondent No.3, CDSCO, supported the impugned orders. The learned Government Pleaders would urge that the Authorities were constrained to take action against the Petitioners, in view of the exigency of the situation. The joint inspection had revealed serious deficiencies and supply of combinations of Tapentadol and Carisoprodol to the local suppliers in India, instead of foreign buyers. The Petitioners have failed to satisfactorily comply with the observations in the inspection report and, therefore, the stop production orders are fully justified.

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1 (1974) 2 SCC 121.

2 2019(1) RLW 769 (Raj.).

3 W.P. No. 7832 of 2018 and W.M.P. No. 9774 of 2018 decided on 18th August 2022.

18. At the outset, it is necessary to keep in view the genesis of the impugned action. Evidently, the action was initiated pursuant to the circular dated 21st February 2025 issued by the CDSCO (R3). The said circular (Exhibit "C" in Writ Petition No. 10603 of 2025) records that the BBC has reported that the combination of Tapentadol and Carisoprodol has significant abuse potential and the said combination was being exported to West-African countries from India. Looking to the potential drug abuse and its harmful impact on public, the Drug Controller General (I), New Delhi, advised all States/UT Drug Controlling Authorities to immediately withdraw all export NOCs and permission to manufacture issued for the combination of Tapentadol and Carisoprodol. The Authorities were requested to withdraw all export NOCs and permission to manufacture issued for all combinations of Tapentadol and all combinations of Carisoprodol which were not approved by the importing country.

19. On 22nd May 2025, Deputy Drugs Controller (India), CDSCO (West Zone), Mumbai, informed the Authorities in the State of Maharashtra, Chhattisgardh, Goa and UT DNH & DD that all export NOCs and permissions issued by CDSCO, West Zone, Mumbai Office for all combinations of Tapentadol and all combinations of Carisoprodol stood cancelled, until further orders.

20. In the wake of the aforesaid advisory and cancellation of the export NOCs and permission, by CDSCO, a joint inspection was conducted at the manufacturing facilities of the Petitioners. As noted above the Petitioners were called upon to furnish the requisite information under Section Section 22(1)(cca) read with Section 18-B of the Act, 1940. The Joint Commissioner, FDA (R1) referred to the joint inspection carried out by the officials of CDSCO and State FDA, the deficiency and the discrepancies noted therein, and directed the Petitioners to stop the production, sale and distribution of medicines under the approved licences till further written orders.

21. It would be contextually relevant to note that, there is no controversy over the fact that the Petitioners surrendered the licences to produce all combinations of Tapentadol and Carisoprodol and the products surrender was approved by the Respondent No.1. Nor it could be disputed that the show cause notices under Rule 85(2) of the Rules, 1945 were issued two days after the respective stop production order.

22. In the backdrop of the aforesaid rather uncontroverted facts, the legality and validity of the order to stop production of medicine under the approved licence is required to be tested. The impact of impugned orders, it must be noted at the cost of repetition, is not confined to combinations of Tapentadol and Carisoprodol, but the very manufacture

of medicines under he approved license for all other products. Can such action be sustained?

23. Rule 85 of Rules, 1945 regulates the procedure for cancellation and suspension of license. In the instant case, we are primarily concerned with the Sub-Rule (2) of Rule 85. It reads thus:

> **"85. Cancellation and suspension of licences**
>
> (1) … … …
>
> (2) The Licensing Authority may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of any of the drugs to which it relates, or direct the licensee to stop manufacture, sale or distribution of the said drugs and thereupon order the destruction of drugs and the stocks thereof in the presence of an Inspector, if in his opinion, the licensee had failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder."

24. A plain reading of Sub-Rule (2) would indicate that the Licensing Authority is empowered to cancel a license or suspend it for such a period as it thinks fit or wholly or in respect of any of the drugs to which it relates, or direct the licensee to stop manufacture, sale and distribution of the specified drugs if, in his opinion, the licensee had failed to comply with any of the conditions of license or with any provisions of the Act or Rules made thereunder. However, there is a

Caveat. The Licensing Authority, before taking any of the aforesaid actions, is enjoined to give the licensee an opportunity to show cause why such an order should not be passed. Moreover, action of cancellation or suspension of license or directing the licensee to stop manufacture, sale or distribution of the specified drugs must be by an order in writing disclosing the reasons therefor.

25. The aforesaid Rule, thus, warrants a pre-decisional hearing in the form of a show cause notice which subsumes in its fold an opportunity to show cause against the proposed action. The Licensing Authority is also enjoined to consider the explanation or cause shown by the licensee and then pass a reasoned order. This obligation to pass reasoned order, post an opportunity to show cause, is impregnated with the requirement of application of mind.

26. It is trite even administrative decisions which impinge upon the fundamental rights and have detrimental civil consequences, are not immune from the imperativeness to adhere to the principles of natural justice. Where there is a statutory requirement to provide an opportunity of hearing, the failure to do so has invariably the vitiating effect. The omission to give an opportunity of hearing where the statute or Rule warrants, constitutes a flagrant violation of a defined decision making process and, in a given case, erodes the very authority to make the decision.

27. In the case of **Nawabkhan Abbaskhan(Supra),** in the context of an Externment order, the Supreme Court enunciated that where hearing is obligated by the statute, the failure to comply with such a duty is fatal. Any act in breach of such a statutory duty is, in its inception, void. The observations of the Supreme Court in paragraph 14 read as under:

> "14. Where hearing is obligated by a statute which affects the fundamental right of a citizen, the duty to give the hearing sounds in constitutional requirement and failure to comply with such a duty is fatal. May be that in ordinary legislation or at common law a Tribunal, having jurisdiction and failing to hear the parties, may commit an illegality which may render the proceedings voidable when a direct attack is made thereon by way of appeal, revision or review, but nullity is the consequence of unconstitutionality and so without going into the larger issue and its plural divisions, we may roundly conclude that the order of an administrative authority charged with the, duty of complying with natural justice in the exercise of power before restricting the fundamental right of a citizen is void and ab initio of no legal efficacy. The duty to hear manacles his jurisdictional exercise and any act is, in its inception, void except when performed in accordance with the conditions laid down in regard to hearing. May be, this is a radical approach, but the alternative is a travesty of constitutional guarantees, which leads to the conclusion of post-legitimated disobedience of initially unconstitutional orders."

28. Closer home to the fact of the case at hand, in the case of **Santokba (Supra),** in the context of Rule 66 of the Rules, 1945, the Rajasthan High Court held that the Licensing Authority is fastened with the liability that before it takes extreme step of either suspending or cancelling the license, at least a notice is required to be given or opportunity to show cause is to be afforded. Once there is a provision in the Rules, 1945 mandating an opportunity of hearing, the Authorities cannot be allowed to plead that the notice to the affected party would be an empty formality.

29. In the case of **M/s Intermed (Supra)**, wherein the Licensing Authority while issuing show cause notice itself had prohibited the licensee from manufacturing or selling the drugs from the premises in dispute, a learned Single Judge of the Madras High Court after adverting to Rule 85(2) of the Rules, 1945 (extracted above) held that from a reading of the Rule, it is clear that the Licensing Authority was required to give an opportunity to licensee and hear him before passing an order. It was clear from the records that no opportunity had been given to the Petitioner before an order was passed. It would be one thing to issue a show cause notice and it is another to require the licensee to stop manufacturing. The Authority therein had passed a rolled up order and required the Petitioner to stop manufacturing while issuing a show cause notice and that was in contravention of Rule 85.

30. In the case at hand, the action of prohibiting the production stands on an even weaker foundation. As noted above, the stop production order was passed two days prior to the issue of show cause notice under Rule 85(2) of the Rules, 1945. No show cause notice, as such, was given before the Respondent No.1 passed the stop production order. The endeavour of Respondents to salvage the position by clinging to the slim thread of the show cause notice, issued after two days of the impugned action, is too fragile to merit countenance. The impugned actions of prohibiting manufacture for sale and distribution of all the medicinal products was in clear violation of the statutory requirements.

31. The Respondents made an endeavour to justify the impugned action by alluding to the potential drug abuse and its grave impact and injurious ramifications on the public *de hors* the failure to comply with the mandatory requirement of the Rule. This submission though attractive at the first blush, looses significance if subjected to close scrutiny. The genesis of the entire action is required to be revisited.

32. As per the Advisory of the Government of India, issued with a view to arrest the potential drug abuse of all combinations of Tapentadol and Carisoprodol, indisputably, both the Petitioners had surrendered the licences to produce the drugs of all combinations of Tapentadol and Carisoprodol, under a couple of days of the said advisory. The Petitioners thus had no subsisting license to produce the

drugs of all combinations of Tapentadol and Carisoprodol. Therefore, the impugned action prohibiting manufacturing of all the medicines of all other products operates onerously and impinges upon the rights of the Petitioners and all the stake holders in the manufacture of the other medicines. Therefore, the endeavour of the Respondents to sustain the impugned action by adverting to the gravity of potential drug abuse cannot be acceded to.

33. The conspectus of the aforesaid consideration is that, the impugned orders deserve to be quashed and set aside. However, it is necessary to clarify that the Competent Authority is free to take appropriate decision in relation to the proposed action of cancellation or suspension of the manufacturing licences, pursuant to the show cause notices issued under Rule 85(2) of the Rules, 1945, in accordance with law.

34. Hence the following order:

: O R D E R :

(i) The Petitions stand allowed.

(ii) In Writ Petition No. 10603 of 2025, the impugned order passed by the Respondent No. 1 dated 22nd February 2025 as well as the order dated 10th July, 2025 passed in Appeal by the Respondent No.2, stand quashed and set aside.

(iii) In Writ Petition No. 10602 of 2025, the impugned order passed by the Respondent No. 1 dated 26th February 2025 as well as the order dated 10th July, 2025 passed in Appeal by the Respondent No.2, stand quashed and set aside.

(iv) It is, however, clarified that the Competent Authority may pass appropriate orders in relation to the proposed action of cancellation or suspension of the manufacturing licence pursuant to the show cause notice under Rule 85(2) of the Rules, 1945, in accordance with law. The observations in this judgment will not be construed as an expression of opinion on the said aspect of the matter.

(v) Rule is made absolute to the aforesaid extent.

(vi) No costs.

[N. J. JAMADAR, J.]