

GAHC010029132023



2026:GAU-AS:5621

THE GAUHATI HIGH COURT
(HIGH COURT OF ASSAM, NAGALAND, MIZORAM AND ARUNACHAL PRADESH)

Case No. : WP(C)/851/2023

M/S ANAMIKA UDYOG
REPRESENTED BY ITS AUTHORISED SIGNATORY RAJENDRA KUMAR,
HAVING ITS REGISTERED OFFICE AT 61/1, MADHUBAN COLONY,
BAGHPAT ROAD, MEERUT AND ITS FACTORY PREMISES AT 127, MULTAN
NAGAR, MEERUT, UP-250002.

VERSUS

PRINCIPAL SECRETARY GOVT. OF ASSAM AND 24 ORS.
HEALTH AND PW DEPTT. 781006

2:OFFICE OF THE MISSION DIRECTOR
NATIONAL HEALTH MISSION
ASSAM
HAVING ITS OFFICE AT SAIKIA COMMERCIAL COMPLEX
SHRINAGAR PATH
CHRISTIAN BASTI
G. S. ROAD
GUWAHATI-781005

3:OFFICE OF THE MANAGING DIRECTOR
ASSAM MEDICAL SERVICES CORPORATION LIMITED

CENTRAL DRUG WARE HOUSE CAMPUS
PATHARQUARY
NARENGI
GUWAHATI
ASSAM-781026.

4:GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
O/O THE ASSISTANT DRUGS CONTROLLER (INDIA) SUB-ZONAL OFFICE
REGIONAL DRUGS TESTING LABORATORY CAMPUS
SIX MILE
PANJABARI ROAD
GUWAHATI-781022

5:OFFICE OF THE MISSION DIRECTOR
ASSAM MEDICAL SERVICES CORPORATION LIMITED
CENTRAL DRUG WARE HOUSE CAMPUS
PATHARQUARY
NARENGI
GUWAHATI
ASSAM-781026

6:THE ASSTT. DRUGS CONTROLLER AND LICENSING AUTHORITY
ARUNACHAL PRADESH
PIN-791110

7:THE ASSTT. DRUGS CONTROLLER AND LICENSING AUTHORITY
MEGHALAYA
PIN-793003

8:THE DRUGS CONTROLLER GENERAL (INDIA)
CDSCO
FDA BHAWAN
NEW DELHI-110002

9:THE DRUGS CONTROLLER
MANIPUR
PIN- 795004

10:THE DRUGS CONTROLLER
MIZORAM
PIN-796001

11:THE DRUGS CONTROLLER
NAGALAND
PIN-797001

12:THE STATE DRUGS CONTROLLER
TRIPURA
PIN-799010

13:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
WEST ZONE

MUMBAI- 400008

14:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
NORTH ZONE
GHAZIABAD-201002

15:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
SOUTH ZONE
CHENNAI-600086

16:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
EAST ZONE
KOLKATA-700020

17:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
ZONAL OFFICE
HYDERABAD
PIN-500038

18:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
ZONAL OFFICE
AHMEDABAD
PIN-380016

19:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
SUB-ZONE OFFICE
BANGALORE
PIN-560001

20:THE DEPUTY DRUGS CONTROLLER(I)
CDSCO
SUB-ZONE OFFICE
BADDI
PIN-173205

21:THE ASSISTANT DRUGS CONTROLLER(I)
CDSCO
SUB-ZONE OFFICE
INDORE
PIN-452001

22:THE ASSISTANT DRUGS CONTROLLER(I)

CDSCO
SUB-ZONE OFFICE
JAMMU
PIN-180001

23:THE ASSISTANT DRUGS CONTROLLER(I)
CDSCO
SUB-ZONE OFFICE
JAMMU
PIN-180001

24:THE ASSISTANT DRUGS CONTROLLER(I)
CDSCO
SUB-ZONE OFFICE
GOA
PIN-403108

25:THE ASSISTANT DRUGS CONTROLLER(I)
CDSCO
SUB-ZONE OFFICE
VARANASI
PIN-22100

**BEFORE
HONOURABLE MR. JUSTICE DEVASHIS BARUAH**

For the Petitioner(s) : Mr. D. Senapati, Advocate

For the Respondent(s) : Mr. B. Gogoi, Addl. A.G.
Dr. P. Agarwal, Advocate

- Date on which Judgment was reserved : N/A
- Date of Pronouncement of Judgment : **23.04.2026**
- Whether the pronouncement is of the Operative Part of the Judgment : No

- Whether the full Judgment has been Pronounced : Yes

JUDGMENT AND ORDER (ORAL)

Heard Mr. D. Senapati, the learned counsel appearing on behalf of the Petitioner. Mr. B. Gogoi, the learned Additional Advocate General appears on behalf of the Respondent Nos. 1, 2 and 3 and Dr. P. Agarwal, the learned counsel appears on behalf of the Respondent No. 7.

2. None has appeared on behalf of the other Respondents.

3. The Petitioner by way of the present writ petition has challenged before this Court the 2 (two) show cause notices issued on 13.02.2022 and 18.06.2022 as well as the communication dated 04.11.2022.

BRIEF FACTS

4. The brief facts leading to the filing of the present writ petition are that pursuant to an e-Tender issued by the Mission Director, National Health Mission, Assam, inviting bids for entering into a rate contract-cum-empanelment of manufacturers to supply of essential surgical, consumables and chemicals, the Petitioner

participated in the said tender process.

5. The tender documents contained various terms and conditions. Clause 22 of the Notice Inviting Tender stipulated "Quality Testing". Clause 25 related to "Quality Control, Deductions & Other Penalties". Taking into account the relevance to Sub-Clauses A, B, and C of Clause 25, the same are reproduced hereinunder:

"A. If the samples do not conform to statutory standards, the supplier will be liable for relevant action under the existing laws and the entire stock in such batch should be taken back by the supplier within a period of 30 days of the receipt of the letter/notice from the tender Inviting authority/Procuring Agency. The stock shall be taken back at the expense of the supplier. Tender Inviting authority/Procuring Agency has the right to destroy such items NOT CONFORMING TO STANDARDS if the supplier does not take back the goods within the stipulated time. Tender Inviting Authority/Procuring Agency will arrange to destroy the items NOT CONFORMING TO STANDARDS within 90 days after the expiry of 30 days mentioned above, without further notice, and shall also collect demurrage charges calculated at the rate of 2% per week on the value of the items rejected till such destruction.

B. If any items supplied have been partially or wholly used or consumed after supply and are subsequently found to be inferior in quality or description or otherwise faulty or unfit for use then the contract price or prices of such items will be recovered from the supplier, if payment had already been made to him. In other words the supplier will not be entitled to any payment whatsoever for items found to be of NOT OF STANDARD QUALITY whether

consumed or not consumed and the Tender Inviting Authority/Procuring Agency will be entitled to deduct the cost of such batch of items from the any amount payable to the supplier. On the basis of nature of failure, the supplier of the product (s) will be liable for Black Listing.

C. In case of supply of items of NOT OF STANDARD QUALITY, the Directorate of Drugs Control be informed for initiating necessary action on the supplier and that product shall be banned and no further supplies accepted from them till they are legally discharged. The supplier shall also not be eligible to participate in tenders of the Tender Inviting Authority for supply of such items for a period of five subsequent years."

6. The said tender also stipulated the items and their quantities in Annexure XIII. The items at serial Nos. 35 and 36 are relevant, as they relate to Roll Bandages measuring 10 cm × 5 meters, 100 grams per dozen and 5 cm × 5 meters, 60 grams per dozen, respectively. The Petitioner, pursuant to the said Notice Inviting Tender was empanelled.

7. Subsequent thereto, supply orders were issued to the Petitioner for Roll Bandages measuring 5 cm × 5 meters and 10 cm × 5 meters to be delivered at various destinations. The Petitioner duly supplied the said roll bandages. Subsequent to the supply of the said Roll Bandages, it was found upon testing carried out by the Central Drugs Laboratory, Government of India, Kolkata, in their reports dated 23.03.2022 and 10.06.2022 that the Roll

Bandages supplied by the Petitioner were not of standard quality. The reports recorded the reason for declaring the samples as "The sample does not conform to Sch. F-II in respect of the tests for Threads per dm, Weight in (gm/m²), Foreign Matter & Fluorescence".

8. Under such circumstances, the Petitioner was issued a show cause notice on 13.02.2022 on the basis of the said report dated 23.03.2022 in respect to the item Roll Bandage, 5 cm. Similarly, in respect to the Roll Bandage 10 cm X 5 meters, the Petitioner was issued another show cause notice dated 18.06.2022 based upon another report dated 10.06.2022 provided by the Central Drugs Laboratory, Government of India, Kolkata. These 2 (two) show cause notices are the subject matter of challenge in the present proceedings.

9. The Petitioner submitted a reply to the show cause notice dated 13.02.2022 on 19.04.2022. In the said reply, which is Annexure-14 to the writ petition, it is mentioned that while the laboratory tested the material, i.e. Rolled Bandage as per Schedule F-II of the Drugs and Cosmetics Act, 1940, the said test is not applicable in the case of the Petitioner's product supplied inasmuch as the testing protocol was not followed as per the tender

condition but was followed as per the Schedule F-II condition. It was further mentioned in the said reply that the materials were supplied by the Petitioner as per the tender condition and the Respondents ought to have checked it with the testing protocol mentioned in the test certificate (weight, length, and weight point). A similar reply was also issued to the show cause notice dated 18.06.2022 by the Petitioner on 22.06.2022.

10. The records further reveal that the Respondent No. 2 made a request to the Assistant Drugs Controller (India), Ministry of Health and Family Welfare i.e., the Respondent No. 4 vide the communication dated 10.05.2022 thereby seeking a technical feedback. The Respondent No. 4 thereupon sought for report from the Drug Controller of India vide a communication dated 29.06.2022.

11. A joint investigation report was prepared by the committee so set up and the said investigation report mentioned that necessary action may be taken against the Petitioner firm by the State Licensing Authority under the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder on the sample of the drug declared, "Not of standard quality", as well as the anomalies found during the inspection/investigation of the firm.

This report is dated 24.08.2022. Interestingly, the said report is not challenged in the instant proceedings.

12. The joint investigation report, thereupon, was forwarded to the Respondent No. 4 by the Deputy Drugs Controller (India) vide the communication dated 02.09.2022. Upon receipt of the said report dated 24.08.2022, the Additional Managing Director of the Assam Medical Services Corporation Limited issued a communication dated 04.11.2022 to the Petitioner to take necessary action on Not of Standard Quality (NSQ) declared batches of Roll Bandage 5 cm and Roll Bandage 10 cm as per the tender clause immediately. This communication dated 04.11.2022 is also assailed in the instant proceedings.

13. The present writ petition was filed on 09.02.2023. This Court vide order dated 22.02.2023, while issuing notice, took note of the show cause notice dated 13.02.2022 and the Petitioner's reply dated 19.04.2022 and observed that no final decision be taken without the leave of the Court. The interim order was thereupon extended from time to time. However, post 07.02.2024, the records do not indicate that the interim order was extended by this Court.

14. In the meantime, pursuant to the issuance of notice the

Respondent No. 2 filed an affidavit-in-opposition justifying the reasons for initiation of the said show cause proceedings, i.e. issuance of the show cause notices dated 13.02.2022 and 18.06.2022, as well as the letter dated 04.11.2022.

15. The Respondent No. 3 also filed an affidavit-in-opposition justifying the initiation of the show cause proceedings against the Petitioner. The Petitioner had also filed a rejoinder affidavit.

16. It is also interesting to take note of an additional affidavit filed by the Petitioner on 26.11.2025 wherein the Petitioner enclosed the debarment notice issued to the Petitioner for 5 years due to furnishing false information about the manufacturing facilities, vide an order dated 29.04.2023. A perusal of the said debarment notice, however, would show that the said debarment notice was issued on the basis of an inspection being carried out by the CDSCO (North Zone) Ministry of Health and Family Welfare, Government of India dated 02.09.2022 and the adverse report so made as regards the manufacturing facility of the Petitioner. It is relevant to take note of that in the said additional affidavit, the Petitioner enclosed a communication issued by the Managing Director of the Assam Medical Services Corporation Limited dated 07.12.2024, whereby the debarment order dated 29.04.2023 was

revoked on the ground that post the debarment notice dated 29.04.2023 the Petitioner had obtained a new manufacturer's license under the Medical Devices Act, 2017.

17. During the course of hearing, this Court inquired with the learned counsel appearing on behalf of the Petitioner as to the letter which was issued by the Petitioner which led to the withdrawal of the debarment order dated 29.04.2023 inasmuch as the communication dated 07.12.2024 mentions that in pursuance to the letter issued by the Petitioner the communication dated 07.12.2024 was issued. The learned counsel appearing on behalf of the Petitioner produced the communication dated 28.11.2024, which was issued to the Managing Director of the Assam Medical Supplies Corporation Limited. The said document, being relevant, is kept on record and marked with the letter "X".

18. In the backdrop of the above factual details, this Court has also heard the learned counsels appearing on behalf of the parties.

SUBMISSIONS MADE BY THE LEARNED COUNSELS FOR THE PARTIES

19. Mr. D. Senapati, the learned counsel appearing on behalf of the Petitioner submitted that the instant writ petition has been

initiated challenging the show cause notices on the ground that the said show cause notices were based upon test reports submitted by the Central Drugs Laboratory, Government of India, Kolkata and the test reports which were carried out were not in consonance with the protocol of the tests which were to be carried out. The learned counsel for the Petitioner therefore submitted that under such circumstances the very show cause notices which have been issued is nothing but a abuse of the process, for which, the same are required to be interfered with in exercise of the jurisdiction under Article 226 of the Constitution. The learned counsel appearing on behalf of the Petitioner further submitted that in the meantime, there was a debarment order dated 29.04.2023 which had been recalled by the Managing Director of the Assam Medical Services Corporation Limited on 07.12.2024 after the Petitioner obtained the license under the Medical Devices Act, 2017. The learned counsel submitted that as the Petitioner has a license under the Medical Devices Act, 2017 the test protocol therefore so followed, which led to the issuance of the show cause notices being not in consonance with law, and more particularly when the Drugs and Cosmetics Act, 1940 would not be applicable, the show cause proceedings are required to be interfered with.

20. Mr. B. Gogoi, the learned Additional Advocate General

appearing on behalf of the Respondent Nos. 1, 2 and 3 submitted that the debarment of the Petitioner vide the order dated 29.04.2023 is completely a separate matter from the initiation of the show cause proceedings, inasmuch as the initiation of the show cause proceedings was on account of supplying Roll Bandages by the Petitioner of inferior quality whereas the debarment order was passed on the ground that while carrying out the inspection, it was found that false information were furnished by the Petitioner as regards the manufacturing facilities. The learned Additional Advocate General further submitted that the very document which is kept on record and marked with the letter "X" clearly shows that the Petitioner duly admit that their manufacturing facilities was not in order at the time of carrying out the inspection, and subsequently the manufacturing facilities were made good, and in pursuance to such manufacturing facilities being made up to date, and inspections being carried out a license was issued and in Form MD5 in terms of the Medical Devices Act, 2017. The learned Additional Advocate General submitted that subsequent thereto, as the Petitioner had improved their manufacturing facilities, the debarment order dated 29.04.2023 was revoked vide the order dated 07.12.2024. The learned Additional Advocate General for the Respondents therefore submitted that the withdrawal of the debarment order vide the

order dated 07.12.2024 is a completely separate aspect which have no relation to the present dispute.

21. Mr. B. Gogoi, the learned Additional Advocate General appearing on behalf of the Respondent Nos. 1, 2 and 3 submitted that the show cause notices were issued to the Petitioner on the basis of certain test reports by the Central Drugs Laboratory, Government of India, Kolkata. The said test reports have not been challenged. The Petitioner thereupon submitted that the tests were not conducted as per the test protocol and it is under such circumstances, the Respondent Authorities have placed the matter before the Respondent No. 4 for technical feedback and the Respondent No. 4 through the Drug Controller (India) had caused an investigation to be made and a report was then submitted on 24.08.2022, opining that the materials so supplied by the Petitioner were not of standard quality. The learned Additional Advocate General further submitted that this very joint investigation report was given to the Petitioner on 04.11.2022, and the Petitioner have not cared to challenge the said joint investigation report. The learned Additional Advocate General submitted that as the show cause notices were issued on the basis of test reports furnished by experts, this Court may not like to interfere, more particularly when the test reports have not been challenged, in exercise of the

jurisdiction under Article 226 of the Constitution.

ANALYSIS AND DETERMINATION

22. This Court has heard the learned counsels appearing on behalf of the parties and has also taken note of the respective submissions.

23. The challenge made in the instant proceedings are to the show cause notices dated 13.02.2022 and 18.06.2022 issued by the Managing Director of the Assam Medical Services Corporation Limited. These 2 (two) show cause notices were issued on the basis of certain test reports submitted by the Central Drugs Laboratory, Government of India, Kolkata dated 23.03.2022 and 10.06.2022. These 2 (two) test reports have not been put to challenge before this Court.

24. Be that as it may, the Petitioner thereupon submitted a reply on 19.04.2022, and in the said reply, the Petitioner urged that the procedure followed in carrying out the tests were not as per the test protocol. The concerned Respondents, thereupon sought for technical feedback from the Respondent No. 4 vide the communication dated 28.05.2022. The Respondent No. 4 in turn sought for a report from the Drug Controller (India) vide

communication dated 29.06.2022, and in pursuance thereto, a joint investigation was carried out by the committee set up by the Drug Controller (India) and a report was submitted on 24.08.2022 wherein also it was opined that the materials so supplied were not of standard quality. This Report was forwarded to the Petitioner vide the communication dated 04.11.2022. Thereupon, the Petitioner approached this Court by filing the present writ petition. It is pertinent to mention that the report of the joint investigation dated 24.08.2022 is also not a subject matter of challenge in the present proceedings.

25. The question therefore arises, as to whether, this Court should exercise the jurisdiction under Article 226 of the Constitution in respect to the initiation of the show cause proceedings by the Managing Director of the Assam Medical Services Corporation Limited?

26. It is well settled that normally the Writ Court should not interfere at the stage of issuance of a show cause notice by the authorities, inasmuch as by issuance of a show cause notice, parties get ample opportunity to put forth their contention before the authorities concerned and to satisfy the authorities concern about the absence of a case for proceeding against the person

against whom the show cause notice had been issued. The reason for not interfering with the show cause proceeding is in order to relegate the parties to the proceedings before the authorities concerned is always considered to be the normal Rule.

27. Be that as it may, there are exceptions to the exercise of jurisdiction under Article 226 of the Constitution in respect to a challenge to a show cause proceedings. They are either when such show cause notice is issued by an authority without jurisdiction, or when such issuance of show cause notice is an abuse of the process of law. In such exceptional circumstances, the Writ Court should not hesitate to interfere even at the stage of issuance of the show cause notice. It is equally important to mention that mere assertion by the Petitioner that the notice is without jurisdiction and/or abuse of the process of law would not suffice. It has to be prima facie established on the basis of materials or on law points which would convince the Writ Court that there is no necessity for any factual adjudication by the Authorities issuing the show cause notice.

28. Let this Court now apply the aforesaid principle to the facts of the present case. It is not the case of the Petitioner that the Managing Director of the Assam Medical Services Corporation

Limited does not have the jurisdiction or authority to issue the show cause notices dated 13.02.2022 and 18.06.2022. Under such circumstances, the question arises, as to whether, the issuance of the said show cause notices is an abuse of the process of law. It is pertinent to observe that both the show cause notices were issued based upon certain test reports provided by the Central Drugs Laboratory, Government of India, Kolkata, or in other words, it cannot be said that the said show cause notices were issued without any materials. It is also apposite to observe that these test reports are provided by experts. This Court does not have the expertise to decide as regards the validity of these test reports. More so, when in the present facts there is no challenge to those test reports.

29. It is also relevant to take note of that even the Respondent Nos. 1, 2, and 3, upon the reply submitted by the Petitioner on 19.04.2022, did not by themselves decide as to whether the test reports were valid. Rather the Respondent Nos. 1, 2 and 3 sought for technical feedback from the Respondent No. 4. In pursuance to such request, a joint investigation report was submitted on 24.08.2022, wherein also it confirmed the test reports which formed the basis of the show cause notices. Under such circumstances, it is therefore the opinion of this Court that the

issuance of the show cause notices cannot be said to be an abuse of the process of law.

30. Consequently, the two exceptions permitting this Court to exercise its extraordinary jurisdiction under Article 226 of the Constitution at the stage of initiation of show cause proceedings being not present there in the instant proceedings, the question of interference with the show cause proceedings do not arise.

31. In that view of the matter, this Court does not find any merit to entertain the present writ petition insofar as the challenge to the show cause notices dated 13.02.2022 and 18.06.2022 are concerned. The letter dated 04.11.2022 is just a communication whereby the Petitioner was duly informed of the joint investigation report and was asked to do the needful and as such, there is no reason for the exercise of the powers of judicial review in respect to the challenge to the said communication dated 04.11.2022.

CONCLUSIONS

32. The instant writ petition stands disposed of with the following observations and directions:

- (i) The challenge to the show cause notices dated

13.02.2022 and 18.06.2022 as well as the letter dated 04.11.2022 is rejected.

(ii) This Court also takes note of that the reports submitted by the Central Drugs Laboratory, Government of India, Kolkata, as well as the joint investigation report dated 24.08.2022, are technical in nature and the Petitioner herein are given the liberty to explain before the authorities concerned that the said reports are either not in consonance with the applicable testing procedures or the said reports have not taken into consideration the required testing protocols. In addition to that, the Petitioner is given the liberty to provide other materials before the Authorities which may lead the authorities not to rely upon the test reports as well as the joint investigation report.

(iii) It is the opinion of this Court that the Respondent No. 2 prior to taking any decision in respect of the show cause proceedings initiated on the basis of the show cause notices dated 13.02.2022 and 18.06.2022, should give a personal hearing to the Petitioner prior to taking any decision, so that the Petitioner can place materials in its defence as per the liberty provided hereinabove.

(iv) Interim order, if any, stands vacated.

(v) No costs.

JUDGE

Comparing Assistant