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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **W.P.(C) 15121/2025 & CM APPL. 62126/2025**

M/S EUROLIFE HEALTHCARE PRIVATE LIMITED

.....Petitioner

Through: Mr. M. Sufian Siddiqui, Mr. Rakesh
Bhugra and Mr. Mohammad Mazhar
Ahmed, Advs.

versus

UNION OF INDIA & ANR.

.....Respondents

Through: Dr. B. Ramswamy, CGSC.

CORAM:

HON'BLE MR. JUSTICE PURUSHAINDR KUMAR KAURAV

ORDER

% **06.01.2026**

1. This petition is directed against the impugned order of debarment dated 11.08.2025, passed by the Office of the Director General Armed Forces Medical Services (DGAfMS), New Delhi. The petitioner claims to be a WHO-GMP and CDSCO-certified pharmaceutical manufacturer of international repute and is engaged, *inter alia*, in the supply of life-saving infusions to the Armed Forces over 36 countries worldwide.
2. The instant petition relates to the product Compound Sodium Lactate injection I.P. and specifically to batch no.DCSL3021 in favour of the petitioner's authorized distributor through Shri Sai Agencies. The total quantity ordered was 10,000 units, which was duly supplied through two batches i.e., Batch No. DCSL3020 (4,150 units) and Batch No. DCSL3021 (5,850 units).



3. It is the case of the petitioner that there was no quality complaint or any issue ever raised by the respondents at any point of time. However, the respondents, by way of the impugned order, have debarred the petitioner without affording a full opportunity of hearing.

4. Mr. M. Sufian Siddiqui, learned counsel appearing for the petitioner has submitted that the impugned order clearly refers to a 'lab test report', and a copy of which has not been supplied to the petitioner. He contends that the show cause notice and the petitioner's reply to the same were meaningless, in absence of a copy of the report having been supplied to the petitioner.

5. Learned counsel has also referred various decisions of the Court, however, reference thereto may not be necessary for the nature of the directions which the Court proposes to be issued.

6. Dr. B. Ramswamy, learned counsel appearing for the respondents, strongly opposes the aforesaid submissions and has relied upon the averments made in the counter affidavit filed by the respondents. He has specifically taken the Court through paragraph Nos.42 to 45, 46 to 47 and 51 to 54. According to him, a copy of the test report by the Central Drugs Laboratory, Kolkata has not been supplied.

7. Dr. Ramswamy submits that the Supreme Court, in the case of ***Amery Pharmaceuticals and Ors. v. State of Rajasthan***,¹ has unequivocally held that there is no necessity to supply the test report and hence, in the instant case, the authorities have made it clear that in case the petitioner so desires, it may take recourse to the exercise under Section 25(3) of the Drugs and

¹ 2001 4 SC 382



Cosmetics Act, 1940 [**‘Act’**] post decision. He also submits that a show cause notice was issued, and the petitioner’s reply was considered. Further, the representation of the petitioner was made before the meeting of the Department. According to him, the impugned order is justified and does not call for any inference.

8. I have considered the submissions made by learned counsel appearing for the parties and have perused the record.

9. A reading of the impugned order dated 11.08.2025 would indicate that the show cause notice was issued to the petitioner on 03.07.2025 and the response thereto was received. It is, thereafter, that the meeting was conducted on 04.08.2025 at the Office of DGAfMS, New Delhi.

10. The plea of the petitioner appears not to have been accepted by the competent authority. However, the petitioner has been advised to take up the matter for retesting as per Section 25 of the Act, if the petitioner is not in agreement with the result of the first test report.

11. The impugned order further states that, awaiting the report or the steps to be taken by the petitioner, punitive action may not be held up and hence, the petitioner has been debarred for a period of two years from the date of passing of the order. For the sake of clarity, the impugned order is extracted below, for reference:

“DEBARMENT OF PVMS NO 270724 COMPOUNDSODIUM LACTATE INJ IP BEARING BATCH NO DCSL-3021, D/M 11/2023, D/E 10/2026 MFG BY M/S EUROLIFE HEALTHCARE PVT LTD, DECLARED AS “NOT OF STANDARD QUALITY”

1. Refer to this office 5567/DGAEMS/DG-2/PCMC/Eurolife/2025:dt 03;Jul 2025, your firm letter No EHPL DGAfMS/04/2025-2026 dt 07/07/2025 and meeting between ADG (E&S) and Mr Shamim Akhtar, General Manager of your firm on 04 Aug 2025 at office of the DGAfMS, New Delhi.

2 Plea of your firm through letter under reference and submission during



aforesaid meeting has not been accepted by competent authority. However, your firm is advised to take up the matter for retesting as per Section 25 of the Drugs and Cosmetic Act 1940 if, your firm is not in agreement with the result of the first test report Punitive action as stated at Para 4 of ibid Show Cause Notice may not be held up because of the same. However, as and when the report of re-testing is received from - appellate authority, the debarment status of subject, drug may be reviewed accordingly by this office. It has been further advised that testing by NABL Labs in this case is not acceptable

3. In view of the above, subject drug of your firm is debarred for two years as per extant policy and instructions have been issued that neither any fresh tender nor supply order will be issued in favour of your firm for subject drug during the debarment period or recovery of the entire cost of the defective batch from your firm, whichever is later. In this, connection please refer to Para 3.5.1 of DPM 2009 & Para 5 (a) & (c) of DoE, MoF O.M. No. F.1/20/2018-PPD dated 02 Nov 2021.”

12. If the reply to the show cause notice is perused, it would indicate that the petitioner had sought immediate retesting of the retention samples of the concerned batch at any alternate CDL or approved NABL-accredited laboratory at the petitioner's cost. Even in *Annexure P-17*, which an e-mail by the petitioner dated 05.08.2025, the aforesaid request was reiterated. This seems to be after the meeting was conducted.

13. It is thus seen that the petitioner, right from the inception, was requesting for retesting of the sample and had not accepted the report of the concerned lab. Even otherwise, a perusal of the material would clearly indicate that the report of the lab has never been supplied to the petitioner.

14. The reply of the paragraph nos.51 to 54 of respondent No.1 reinforces the aforesaid position, which states that as per Section 25 (3) and (4) of the Act power to allow retesting is vested in the Drug Inspector or the Court. The respondents do not dispute the right of the petitioner for getting the sample retested, however, what is contended is that the aforesaid right can be exercised post decision.



15. The averments made in the reply to paragraph Nos.46 to 47 of the petition will also have relevance and accordingly, the same is extracted below, for reference:

“Para 46 to 47- The petitioner's claim of violation of natural justice and denial of the statutory right to appellate retesting under Section 25 of the Drugs and Cosmetics Act is wholly misplaced as the debarment order was passed after due consideration of the available test report and after affording opportunity to the petitioner through Show Cause Notice dated 03.07.2025, to explain and rebut the test findings. s. / The office held meeting with the petitioner's representatives, including documented minutes, to encourage all remedies available under Section 25 of the Drugs and Cosmetics Act, 1940 and ensure statutory safeguards. The contention that the petitioner was denied Form 13 or the complete analysis report is refuted. The said documents were provided, albeit belatedly, and any delay in furnishing the documents does not vitiate the legality of the impugned order especially when the petitioner failed to timely (pursue its appellate rights. Moreover, the firm was aware of the matter since Mar 2025 as evident from the letter dated 31.03.2025 addressed to the Deputy Drugs Controller (India), &W Delhi by the firm. The petitioner's assertion that the) Barment was imposed without allowing retesting is incorrect

The petitioner was advised in the impugned order that it could seek retesting under Section 25 if dissatisfied with the test results and the debarment was made subject to the outcome of such retesting.

Para 48- That in reply to the contents of Para, it is submitted that the contents of this Para need no reply from the Respondent No 1 as these are pertaining to CDSCO (Respondent No 02).”

16. A cumulative reading of the material would thus establish that the lab report remains unserved to the petitioner.

17. If Section 25(3) of the Act is perused, it would indicate that any document purporting to be a report signed by Government Analyst under Chapter-IV shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of



the report, notified in writing to the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

18. In the instant case, what assumes significance is the fact that the right to controvert the report has not yet commenced and punitive action has already been taken by the respondents. As on date, no proceeding pertaining to the report remains pending before any Court. What is assailed by the petitioner is the decision taken on the basis of the report. Since, till date, the report has not been supplied to the petitioner, therefore, the petitioner has not been able to exercise its right of controversion to the said report vested under Section 25(3) of the Act.

19. The impugned order thus suffers from material illegality and is in violation of the principle of natural justice. No meaningful opportunity of hearing can be said to have been granted to the petitioner in absence of the material which forms basis of the impugned action. The impugned order, therefore, deserves to be set aside. The same is accordingly set aside.

20. The respondents, however, are granted liberty to supply a copy of the test report and to enable the petitioner to exercise the right of controversion and to take the matter to its logical end without being influenced by any of the observations made herein.

21. With the aforesaid direction, the petition stands disposed of alongwith the pending application.

PURUSHAINDRA KUMAR KAURAV, J
JANUARY 6, 2026/p/amg