$~21

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

\+ W.P.(C) 776/2024 & CM APPL. 3379/2024, CM APPL. 3380/2024

LUCKY PHARMA LOGISTICS PRIVATE LIMITED

.....Petitioner

Through: Mr. Preetam Singh, Advocate.

versus

LIEUTENANT GOVERNOR, GNCTD & ORS. .....Respondents

Through: Mr. Santosh Kumar Tripathi, Standing Counsel with Mr. Kartik Sharma and Mr. Rishabh Srivastava, Advocates for GNCTD.
Mr. Rohit Bajpai, Assistant Drug Controller and Mr. Hemant Kumar, Drug Inspector.
Mr. Viraj R. Datar, Senior Advocate with Mr. Ashish Verma, Mr. Kartikey Bhargava, Mr. Srikant Singh and Mr. Rajat Bhatia, Advocates for R-4.

CORAM:
HON'BLE MR. JUSTICE SANJEEV NARULA

O R D E R

% **30.08.2024**

1. The present petition assails order dated 08th November, 2023 passed by Respondent No. 1 rejecting Petitioner's appeal against order dated 24th August, 2023,[1] passed by the Assistant Drugs Controller and Licensing Authority, Drugs Control Department, Government of NCT of Delhi. Through the aforesaid orders, Petitioner's four drug licenses were cancelled

[1] *collectively*, "the impugned orders"

on the ground that the drug *'Rosuvas 10 Mg'*, [2] manufactured by Respondent No. 4/ Sun Pharma Laboratories Limited,[3] is not of standard quality as Petitioner contravened in violation of Section 18(a)(i) read with Section 17B(e) of the Drugs and Cosmetics Act, 1940,[4] and Rule 65(5) of the Drugs Rules, 1945.[5]

2. A brief background leading to the filing of the present petition is as follows:

2.1. The Petitioner is engaged in the business of wholesale and supply of drugs. On 14th February, 2023, they were granted four licences to sell, stock, or exhibit for sale or distribute by retail/ wholesale in respect of permitted drugs, which were valid till 13th February, 2028. The details of the said licences are as follows:

License Number	**Form No.**	**Category**	**Particulars**
DL-TGB-154980	Form 20	Retail	Drugs other than those specified in Schedule C, C(1) and X
DL-TGB-154981	Form 20(B)	Wholesale	
DL-TGB-154982	Form 21	Retail	Drugs specified in specified in Schedule C, C(1) and X
DL-TGB-154983	Form 21(B)	Wholesale	

2.2. Pursuant to a complaint received from Sun Pharma, the Drugs Department conducted a raid on 20th May, 2023 at the premises of the Petitioner and M/s A.R. Pharma. During the raid, the team discovered a stock of 40x01x10x15 tablets of *Rosuvas* 10 Mg (Rosuvastatin Tablets IP) bearing batch No. SID3056A at the Petitioner's premises. The raid was conducted in the presence of Mr. Narinder Ahuja, General Manager of

[2] "the drug in question"
[3] "Sun Pharma"
[4] "the Act"

Corporate Relations at Sun Pharmaceuticals Industries Limited. Upon a physical examination of the samples recovered from the Petitioner's premises and those of A.R. Pharma, Mr. Ahuja observed that the tablets did not appear to have been manufactured by Sun Pharma. Accordingly, the samples bearing stamp HK/07/2023 and HK/08/2023 collected from Petitioner and A.R. Pharma respectively, were sent for a test report. In the test, the sample failed and Government Analyst, Regional Drugs Testing Laboratory, Chandigarh, declared it *"not of standard quality"* as the same *"does not conform to claim as per IP 2018 in respect of Description and Assay of Rosuvastatin Calcium"*. Additionally, in a report dated 29th June, 2023, Sun Pharma also confirmed that the specimens were spurious.

2.3. Subsequently, on 17th July, 2023, Respondent No. 2 required the Petitioner to show cause as to why their licenses should not be suspended or cancelled in light of the spurious drugs discovered on their premises. In their response, the Petitioner asserted that the drug in question had been purchased from A.R. Pharma under valid invoices. However, after considering the Petitioner's reply, Respondent No. 2 issued the impugned order dated 24th August, 2023, cancelling all four of the Petitioner's licenses in the public interest.

2.4. Aggrieved from the same, Petitioner challenged the said order before Hon'ble Lieutenant Governor, GNCTD. In the impugned order dated 08th November, 2023, it was observed that since the Petitioner is admittedly a distributor for Sun Pharma, their plea under Section 19(3) of the Act is not applicable. The provision under Section 19(3) is not available to a person who is either a manufacturer of a drug or an agent responsible for its

---

[5] "the Rules"

distribution.

3. In this background, Mr. Preetam Singh, counsel for Petitioner contends that the impugned orders are liable to be set-aside as the Petitioner is entitled to the benefit of the afore-mentioned provision. He argues that the Petitioner exercised due diligence in conducting their retail activities and that this act of omission was neither instigated nor connived by them. The Petitioner had been regularly purchasing drugs from A.R. Pharma, who holds a valid drug license from the Drugs Department, and thus, could not have reasonably known that the drugs they bought were spurious. Furthermore, he submits that the Petitioner is a regular purchaser of the drug in question from Sun Pharma's CFA agent, Sun Pharma Distributors Limited, having purchased the drug for approximately INR 43 crore over the span of one year. The specimen recovered from their premises were part of a small transaction with A.R. Pharma, amounting to INR 1,82,917/- across three tranches. Additionally, he submits that the impugned order dated 08th November, 2023 has wrongly noted that the Petitioner is admittedly a "direct distributor" of the Sun Pharma when no such admission to this effect was given by the Petitioner. The Petitioner is entitled to the benefit provided under Section 19(3) of the Act and Rule 66 of the Rules. In this regard, he also submits that the Stockist Agreement dated 01st April, 2023 between the Petitioner and Sun Pharma only bears the signature of Petitioner's representative and is not signed by Sun Pharma, therefore, the said Agreement was never executed. Furthermore, he argues that the penalty of cancelling all four licenses is bad in law as only two licenses concern the drug in question. This has resulted in the Petitioner's business being brought to a standstill. Moreover, he argues that there is no purity in the supply chain

of drugs which makes the retailers vulnerable.

4. *Per contra*, Mr. Viraj R. Datar, Senior Counsel for Sun Pharma states that the drug in question is prescribed for treatment of high cholesterol and prevention of heart attack. The efficacy of the counterfeit drug found from the Petitioner's premises was found to be merely 27.85% which could lead to serious health concerns for patients consuming the same. He submits that the Petitioner is admittedly the distributor of Sun Pharma as has also been recorded in the impugned order. Even prior to signing of the Stockist Agreement, the Petitioner had purchased the drug in question from Sun Pharma, therefore, he was well-aware of the difference in price of the said drug offered for sale by A.R. Pharma and Sun Pharma. Thus, Petitioner's transaction with A.R. Pharma cannot be said to be innocent or with reasonable diligence. In such circumstances, Petitioner cannot invoke Section 19(3) of the Act.

5. The Court has extensively heard counsel for parties. The counsel for Petitioner requests that he may be afforded another opportunity to put forth his case before the Respondent authorities as concededly, their initial reply did not raise the factual and legal defences.

6. It emerges that during the appeal proceedings before Lieutenant Governor, the Petitioner invoked Section 19(3) of the Act. On a bare reading of the provision, it is observed that Section 19 is a defence in prosecution proceedings initiated under Chapter IV of the Act. Upon a query of the Court, it has been pointed out that prosecution proceedings against Petitioner have not yet been launched and the present dispute concerns the cancellation of Petitioner's licences under Rule 66 of the Rules. Although in the present writ proceedings, counsel for Petitioner has advanced submissions on Rule

66, however, neither in the reply to the Assistant Drug Controller and Licensing Authority nor in the appeal proceedings, such a defence was raised with material to support such a contention. It is also noted that although the two provisions have a common thread, yet they are differently worded. However, none of the other grounds as urged before this Court have been presented before the Assistant Drugs Controller and Licensing Authority and the Lieutenant Governor. For ease of reference, the provisions are represented below:

The Drugs and Cosmetics Act, 1940	**The Drugs Rules, 1945**
*"**19. Pleas.-*** *xx … xx … xx* *(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—* *(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;* *(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and* *(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it."*	*"**66. Cancellation and suspension of licences. –*** *(1) The licensing authority may, 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 some of the substances to which it relates, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules thereunder:* *Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority-* *(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or* *(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of*

	that previous act or omission, or *(c) if the act or omission was a continuing act or omission, he had not or could not reasonably have had knowledge of that previous act or omission, or* *(d) that he had used due diligence to ensure that the conditions of the licence or the provisions of the Act or the rules thereunder were observed.* *(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.*

7. Considering the foregoing, it is evident that the Petitioner has, thus far, argued their case before the Respondent authorities based on an incorrect premise, specifically by invoking Section 19(3) of the Act, which primarily applies in the context of prosecution proceedings rather than the regulatory actions under Rule 66. Additionally, Petitioner's initial reply failed to adequately elaborate on the factual and legal defences relevant to the cancellation of their licenses under Rule 66. This has deprived the Petitioner of a full and fair opportunity to present their case, particularly in light of the distinct considerations under Rule 66 that may afford a different outcome.

8. In light of the facts noted above since the Petitioner's defence was not fully articulated before the Assistant Drugs Controller and Licensing Authority, nor during the appeal to the Lieutenant Governor, it is only just and proper to allow the Petitioner an opportunity to rectify this omission. The interests of justice demand that the Petitioner be permitted to submit a comprehensive representation that accurately addresses both the factual

circumstances and the legal framework governing the cancellation of licenses.

9. Accordingly, the present petition is disposed of with a direction that the Petitioner shall be permitted to submit a detailed representation to the Assistant Drugs Controller and Licensing Authority. The said Authority shall consider the Petitioner's representation independently and without being influenced by the observations made in the impugned orders. The Authority is further directed to adjudicate the matter strictly in accordance with law, ensuring that all relevant facts and legal arguments are thoroughly examined before rendering a decision. In case the order is adverse to the Petitioner's interest, they shall be at liberty to assail the same, in accordance with law.

10. All rights and contentions of parties are left open.

11. The present petition, along with pending applications, if any, is disposed of.

SANJEEV NARULA, J

AUGUST 30, 2024
d.negi