IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 27.02.2024

CORAM:

THE HON'BLE MRS.JUSTICE T.V.THAMILSELVI

CRL.OP No. 18434 of 2022
& Crl. MP. Nos. 12157 & 12160 of 2022

1 M/S.ASPEN LIFE SCIENCES
REP BY PARTNER SHRI PEEYUSH SHARMA PLOT NO. 57 NAGKALAN INDUSTRIAL AREA MAJITHA ROAD AMRITSAR 143 601.

2 SHRI PEEYUSH SHARMA
PARTNER M/S. ASPEN LIFE SCIENCES NO.57 NAGKALAN INDUSTRIAL AREA MAJITHA ROAD AMRITSAR 143 601.

3 SHRI ASHISH GARG
PARTNER M/S. ASPEN LIFE SCIENCES NO.57 NAGKALAN INDUSTRIAL AREA MAJITHA ROAD AMRITSAR 143 601.

[PETITIONERS]

Vs

1 THE STATE OF TAMIL NADU
REP BY DRUGS INSEPCTOR CHROMPET RANGE O/O. THE ASSISTNAT DIRECTOR OF DURGS CONTROL KANCHEEPURAM ZONE CHENNAI 600 006.

[RESPONDENTS]

PRAYER : This petition has been filed under Section 482 of Cr.P.C, to call for the records and quash the complaint filed by the respondent in C.C.471 of 2022 for the offences u/s. 18(1)(a) of the Drugs and Cosmetics Act 1940 which is punishable u/s. 27 (d) of Drugs and Cosmetics Act 1940 on the file of the Chief Judicial Magistrate at Chengalpattu.

For Petitioners : Mr.S.Janarthanan
For R1 : Mr.S.Vinoth kumar,
Government Advocate crl. side

ORDER

The petitioners herein filed this petition to call for the records and quash the complaint filed by the respondent in C.C.471 of 2022 for the offences u/s. 18(1)(a) of the Drugs and Cosmetics Act 1940 which is punishable u/s. 27 (d) of Drugs and Cosmetics Act 1940 on the file of the Chief Judicial Magistrate at Chengalpattu.

2. The case of the prosecution is that the Drug Inspector, Chrompet Range, taken sample of Esnocold Suspension (Paracetamol Phenylephrine Hydrochloride and Chlorpheniramine Maleate Suspension) B.No A10385, Date of Mfg Feb/2019, Date of Exp: Jan/2021, Mig by: Asper Life Sciences, Plot No 57, Nankalan Industrial Area, Majitha Road Amritsar-143601, was

drawn for analysis by the Complainant from M/s Shri Agencies Door.No 6 Portion of Ground Floor Nehru Street Bharathipuram Chrompet Chennai -44 under Form 17 and the same was sent for analysis to the Government Analyst (Drugs), DTI, Chennai-6 under Form 18. Thereafter, the sample has been declared as not of Standard Quality by the Government Analyst (Drugs), Drug Testing Laboratory, Chennai under Form 13 for the reason that the sample does not conform to label claim with respect to the content of Phenylephrine Hydrochloride. Therefore, it is a violation under Section 18 (a) (i) of the Drugs and Cosmetics Act 1940 and rules 1945. A memo dated 24.10.2019 was issued to M/s Shri Agencies and in their reply dated 24.10.2019, stated that the subject drug was purchased from from M/s Olens Healthcare Private Limited Shop. No 20. 2nd Floor Old Ropar Road Manimajra Chandigarh-160101 and Quantity received was 100x60 ml under invoice, No0001865 dated 08.03.2019. Subsequently, memo dated 04.11.2019 was issued to M/s Olens Healthcare Private Limited Shop and they have stated in their reply dated 18.11.2019, that the subject drug was purchased from M/s. Aspen Life Sciences. Further a memo dated 26.11.2019 was issued to M/s Aspen Life Sciences, hereby directed to explain as to why action should not be taken for the contravention of Section

18 (a) (i) of the Drugs and Cosmetics Act 1940 and Rules 1945 for having manufactured for sale and sold the Not of Standard drug and also directed them to submit the particulars under Section 18B of the said Act. The reply to the memo dated 11.12.2019 was received on 16.12.2019 from M/s Aspen Life Sciences, stating that the subject drug was released after the approval of in house laboratory report and they have also stated that sample may not stored properly or due to direct exposure to sunlight may lead to quality issue. They have also mentioned that Phenylephrine Hydrochloride should be stored at room temperature and protected from direct sunlight while the retailers might not stored properly. The reply submitted by the above said firm was not satisfactory. Hence complainant has submitted the proposal for prosecution dated 31.12.2019 to the Director of Drugs Control, Tamil Nadu to prosecute for contravention of Section 18(a) (i) of Drugs and costmetics act 1940 made there under for having manufactured for sale and sold Not of Standard quality Drug, namely Esnocold Suspension" which is punishable under Section 27(d) of the said Act. Thereafter, the Trial Court taken the case on file in C.C No. 471 of 2022. Hence, the petitioner filed this petition to quash the same.

3. The learned counsel for the petitioner submits that the petitioner is having valid license to manufacture the drug namely "Esnocold Suspension" in the form of oral suspension which is a Paracetamol Phenylephrine Hydrochloride and Chlorphniramine Maleate Suspension used for treating cold and cough. A sample of drug was taken into inspection by the complainant from a retailed M/s.Shri Agencies which was purchased from marketer M/s. Olens Healthcare Pvt. Ltd., and on analysis, it was mentioned that the drug was not of standard quality. The complainant issued the memo to the company and the same was replied that the drug would have been affected due to improper storage conditions along with the influence of sunlight by the retailer and the company gave a proper reply without considering their reply the prosecution initiated the proceedings against the company for the offence under Section 18(a) (i) of Drugs and Consmetics Act 1940 and Rules 1945 as such is erroneous one. Further, the complainant clearly failed to look into the guidelines for taking action on samples of Drugs declared spurious or not of standard quality in the light of the enhanced penalties under the Drugs and cosmetics Act, 2008 issued by the Central Drugs Standard Control organization to which the complainant is bound upon. Further, he submits that if at all any minor discrepancies that

would not amount to prosecute under Section 18(a) (i) of Drugs and Cosmetics Act to that effect relied the judgement of this Court in Crl. O.P No. 23942 of 2015 in the case of Embiotic Laboratoried Pvt. Ltd. Vs. Union of India.

> 9. Before adverting to the rival contentions, it is worth while to refer Section 33 P of Drugs and Cosmetics Act, 1940, in which Categories B & C, reads as follows:- "Category B (Grossly sub-standard drugs) (iii) Tablets / Capsules failing in dissolution test and active contents found less than 70% for thermo labile products and below 5% of the prescribed limits for thermo stable products. Tablets/Capsules failing in dissolution test and active contents found less than 70% for thermo labile products and below 5 % of the prescribed limits for thermo stable products In the case of drugs manufactured by a licensed manufacturer under a valid manufacturing licence and found grossly substandard and where criminal intent or gross negligence is not established, weapon of prosecution should be used judiciously, where it is felt that administrative measures like suspension or cancellation of licenses or compounding of offences would not meet the ends of justice.

4. In the present case, laboratory report shows that active ingredient contents below 79.36 % which is minor discrepancy for that they need not be prosecuted. Further, he relied the another judgment of this Court in Crl.O.P No. 29180 of 2017:

> 10. It is also relevant to note that prior to the amendment of Rule 109A, the position of Rule is that the labeling of medical devices was confirmed to the Indian specifications laid down from time to time by the Bureau of Indian Standards in addition to any other specification provided in the said Rules. Indian Standard with regard to the infusion of equipment for medical use of the years 2003 and 1998 appended to the typed set particularly the Rule 9(1) require only year and month of expiry and name of manufacturer, or supplier's place and address alone to be printed on the infusion equipment. It has been done. Therefore, under Rule 96(1)(xii) the

import license is not required at the relevant point of time when the sample was taken on 06.02.2014, which is prior to the amendment of Rule 109A. 11. Further, the report of the Government Analyst itself indicates that the sample sent to the analysis is of the standard quality and had passed Sterility Test, BET Test, Abnormal Toxity Test. In such view of the matter, this Court is of the view that initiating of prosecution for violation of the Rules which was introduced at a later point of time, much after the sample is lifted and inspection is carried out, is nothing but a futile exercise.

5. On perusal of the records, in the present case as per the report of the Drug Analyst it is not of standard quality. Further, the authorities relied by the petitioner is for category B the petitioner have to prove the same at the time of trial whether the drug is under B or C category. It is a matter for trial. I am not inclined to allow this petition. However, the appearance of second and third petitioner is ordered to be dispensed with.

6. In the result, this petition is dismissed. No Costs. Consequentially, connected miscellaneous petition(s) are closed.

27.02.2024

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T.V.THAMILSELVI, J.

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To

1. The Public Prosecutor, High Court, Madras.

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