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

% ***Reserved on: 24th March, 2025***
Pronounced on: 27th June, 2025

\+ **W.P.(CRL) 3588/2016 & CRL.M.A. 19498/2016 (Stay)**

M/S ZEE LABORATRIES
Through Sh. Chander Shekhar,
Authorized Representative of Petitioner
47, Gondpur Industrial Area,
Paonta Sahib, District Sirmour,
Himachal Pradesh. ....Petitioner

Through: Mr. Vishesh Wadhwa, Ms. Swadha Gupta and Mr. Vishwash Mishra, Advocates.

versus

1. UNION OF INDIA
Through Secretary,
Ministry of Health and Family Welfare
Nirman Bhawan, Maulana Azad Road,
New Delhi - 110011 .....Respondent No.1

2. CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Through Drugs Controller General of India
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India FDA Bhavan, ITO,
Kotla Road, New Delhi - 110002 .....Respondent No.2

Through: Ms. Arunima Dwivedi learned CGSC with Ms. Swati Jhunjhunwala, Ms. Pinky Pawar, Advocates for UOI.

\+ **W.P.(CRL) 3592/2016 & CRL.M.A. 19520/2016 (Stay)**

M/S ZEE LABORATORIES

Through Sh. Chander Shekhar,
Authorized Representative of Petitioner
47, Gondpur Industrial Area,
Paonta Sahib, District Sirmour,
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CORAM:
HON'BLE MS. JUSTICE NEENA BANSAL KRISHNA

J U D G M E N T

NEENA BANSAL KRISHNA, J.

1. Petitions under Article 226 of the Constitution of India under Section 482 of the Code of Criminal Procedure, 1973 (*hereinafter referred to as "Cr.P.C."*) has been filed to challenge the Summoning Order dated 07.12.2015 in *Criminal Complaint No.15/4 of 2015 and 16/4 of 2015* filed

by the Drug Inspector, Sh. Dharmvir Singh under ***Section 18(a)(i) read with Section 16*** and punishable under ***Section 27(d) of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as "D&C Act")***.

2. ***Briefly stated***, the Petitioner, M/s. Zee Laboratories is a Partnership Firm involved in the manufacturing of Pharmaceutical products, having its manufacturing unit at Paonta Sahib, District Sirmour, Himachal Pradesh. The Petitioner manufactures drug, "*KETZY EYE DROPS" (Ketorolac Tromethamine 0.5% Ophthalmic Solution)"* licensed with State of Himachal Pradesh.

3. The **Complainant/Respondent No.2** asserted in its aforesaid two Complaints, both dated 10.08.2015, that Sh. Rajeev Mukul and Sh. Tarun Kumar are the Partners of the Petitioner Firm and *responsible persons* for its affairs at the time of manufacture of drugs in question. They were also *in charge and responsible for the conduct of the business of the Firm.*

4. The Complainant/Respondent No.2 asserted that on 26.09.2013, Drugs Inspector Dharmvir Singh, inspected Guru Gobind Singh Govt. Hospital, Raghubir Nagar New Delhi (GGSGH) and took ***three samples of*** the drug "KETZY EYE DROPS", on Form-17 for testing and analysis under Section 23 of the D&C Act and Drugs and Cosmetics Rules, 1945 (*hereinafter referred to as "D&C Rules"*). The details of the samples collected are as follows;

BATCH NO.	DATE OF MANUFACTURING	DATE OF EXPIRY
EEZ651	03/2012	02/2014
EEZ652	05/2012	04/2014
EEZ653	07/2012	06/2014

5. Drugs Inspector, Dharmvir Singh offered fair price of the drugs to Dr. Alka Gabrayal, Medical Officer In-charge, GGSGH, but she refused to accept the fair price. The Complainant/Respondent no.2, Drugs Inspector then filled up Form 17A as per Rule 56-A and 145-AA as the drugs kept for distribution in Government Hospital, were not for sale and handed over the copy of Forms to Dr. Alka Gabrayal.

6. The seized samples were sent to ***Government Analyst, Central Drugs Laboratory, Kolkata*** in Form 18 Memorandum dated 27.09.2013. The CDSCO, Head Quarters, New Delhi received the letter dated 25.10.2013 from the Government Analyst, Central Drug Laboratory, Kolkata for arranging complete specifications of the Products, complete method of analysis and Ketoroiac Tromethamine working/reference standard for testing of "KETZY EYE DROPS". This Letter dated 25.10.2013 was forwarded to the Petitioner Firm with a forwarding letter dated 14.11.2013 with directions to provide the details as sought therein.

7. The Petitioner Firm vide letter dated 19.12.2013 addressed to CDSCO, Hqrs. New Delhi, gave the requisite intimation about the complete specification of the product, complete method of analysis and Ketoroiac Tromethamine working/reference standard for testing of KETZY EYE DROPS".

8. *The Report, in respect of Sample of Batch No. EEZ652* from Central Drugs Laboratory, Kolkata was received on 27.12.2012***(sic***) wherein the Sample was reported to be as **"*Not of Standard Quality*"** with a reason "***Extractable Volume***". Vide Corrigendum Letter dated 31.12.2013, the date of Test Report was corrected to 27.12.20**13** instead of 27.12.20**12**.

9. *The Reports in respect of Sample of Batch No. EEZ651 & EEZ653* from Central Drugs Laboratory, Kolkata was received on 03.02.2014 wherein it was reported as **"*Not of Standard Quality*"** with a reason that "***the samples do not conform to claim with respect to the sterility test***."

10. The copy of the Test Reports was forwarded by the Complainant/Respondent No.2, to Dr. Alka Gabrayal, Medical Officer In-charge, GGSGH, under Section 25(2) of the D&C Act along with the Show Cause Notice under Section 18A and 18B of the D&C Act, vide Letter dated 06.01.2014 and Letter dated 07.02.2014 with a request to disclose the name, address and the particulars of the person from whom they had acquired the Drug along with the documents.

11. In response to the Show Cause Notice, Dr. Alka Gabrayal disclosed the particulars in Form 18A and 18B of the D&C Act, vide Letter dated 08.01.2014. It was informed that the *Eye Drop Drug* had been manufactured by the Petitioner Firm in Himachal Pradesh and had been received by her on 16.06.2012, vide Invoice No.04118 and on 31.03.2012 & 04.08.2012 vide Invoice No. 19744 & 06758, respectively.

12. The Complainant/Respondent No.2 then issued a *Show Cause Notice* under Section 18B of Drugs & Cosmetics Act and a Notice dated 09.01.2014 and dated 10.02.2014, respectively, along with the original copy of the Test Report dated 27.12.2013 and 03.02.2014 along with one sealed sample portion as required under Sections 25(2) & 23(4)(iii) of the D&C Act respectively, to the Petitioner Firm. The Complainant/Respondent No.2 also directed the Petitioner Firm to stop the sale of drug in question and withdraw the stock of the sample drug from the market, where they had been

sold and also directed to submit the certified copies of documents pertaining to manufacturing, testing and also to furnish distribution details relating to aforesaid drug and constitution details of the Firm and recall status of the subject drug.

13. The Petitioner Firm sent a letter dated ***Nil*** with reference to letter dated 09.01.2014, which was received by the Complainant/Respondent No.2 on 25.02.2014, stating that the control sample in their possession was complying the test for ***Extractable Volume*** and All Tests were within the limit. The Petitioner Firm also submitted its Manufacturing licence, copy of Certificate of Analysis of finished product, Batch manufacturing record and Master Formula record.

14. Petitioner Firm upon receiving the said Show Cause Notice dated 10.02.2014, sent a Letter dated 25.02.2014, to the Respondent No.2, stating that the control sample in their possession was complying the test for ***sterlity*** and all Tests were within the limit and therefore, they wish to adduce evidence in controversion of the Test Report.

15. However, it did not submit certified copies of the Firm constitution details, copy of Memorandum, Article of Association, names and residential addresses of the Partners responsible for day-to-day conduct of business and the names and addresses of Production Chemist/competent person, analytical chemist/competent technical person responsible for production activities and analytical activities respectively of not of quality standard drugs batches.

16. The Deputy Drug Controller (India) directed the action to be taken against the Petitioner's Firm under the provisions of D&C Act vide its Letter

dated 13.01.2014 & 10.02.2014. The Assistant Drugs Controller-cum-Drugs Licensing Authority, Distt. Simour at Nahan, Himachal Pradesh also suspended the permission of manufacturing of the said product for 90 days since 19.05.2014 to 16.08.2014, vide its letter dated 12.05.2014.

17. The permission to launch the prosecution against the Petitioner/accused persons was accorded by the Drugs Controller General (I) vide Office Order dated 13.06.2014 from the Controlling Authority. **The two aforesaid Complaints thereafter, were filed under Section 18(a)(i) read with Section 16 and punishable under Section 27(d) of the Drug and Cosmetics Act.**

18. Summons was issued by Ld. MM, Tis Hazari and the Complaint was withdrawn due to some technical reasons. Thereafter, the summons was issued by the Ld. MM. Rohini and Respondent No.2 had appeared on 21.07.2014 and 11.08.2014.

19. The ***Ld. MM*** on the Application of the Petitioner for re-testing, observed that since the drugs namely KETZY EYE DROPS [Ketorolac Tromethamine Ophthalmic Solution) Batch No EEZ651 Date of Manufacturing 03/2012, has expired on February2014 and Batch No. EEZ653 having date of manufacturing as 07/2012, has expired on June,2014, no purpose would be served by sending the samples for retesting to CDL, Kolkata and the said Application was accordingly disposed of.

20. The Ld. MM on 07.12.2015 took cognizance on both of the Complaints and issued summons against the Petitioner. Aggrieved, the present Petitions have been filed to challenge the ***Summoning Order***.

21. ***The grounds of challenge are that Section 25(3) of the D&C Act gives a valuable right to the accused to rebut the conclusive nature of the Report of Government Analyst,*** by notifying its intention to adduce evidence in contravention of the Report before the Drug Inspector or before the Court where the proceeding in respect of said sample is pending. No proceedings were pending before any Court when the Petitioner were served with the Government Analyst report. However, the Drug Inspector was obligated to institute Complaint forthwith and produce Sample and request the Court to send the sample for analysis and test to the Director, Central Drugs Laboratory.

22. The Petitioner have been deprived of their right to have the samples examined by the Director of the Central Drugs Laboratory. Therefore, the prosecution initiated vide the Complaint, is vitiated on account of denial of valuable right of seeking testing as guaranteed to the Petitioner under Section 25(4) of the Act.

23. Reliance is placed on the case of *State of Haryana Vs. Bhajan Lal*, 1992 Supp (1) SCC 335 wherein the Apex Court observed that the criminal proceedings may be quashed at threshold, if the Complaint taken on its face value does not disclose any offence or is in violation of mandatory provisions of law.

24. It is emphasized that the conduct of the Drug Inspector has resulted in complete denial of right under Section 25(4) to the Petitioner. The drug had expired much prior to the filing of the Complaint consequent to which his right to get the second sample sent for examination by Central Laboratory has been frustrated.

25. It is further submitted that ***Form 17*** does not provides for the storage condition of the samples collected by the Respondent No.2, Drug Inspector. The Petitioner had complied with all the provisions of D&C Act in the manufacturing of the said drug.

26. The Drugs Controller while considering the matter, suspended the permission of the Petitioner to manufacture the drug as per the guidelines of D&C Act, thereby punishing the Petitioner. This was duly informed to the Complainant, Drug Inspector, but he ignored the facts and launched the prosecution with *mala fide* intent. The Petitioner have already been punished by the State Drug Controller, Himachal Pradesh. The Respondent No.2/Complainant, Drug Inspector could not have on its own decided for suspension of permission of manufacturing of the product for 90 days. *He cannot be penalized twice for the same offence.*

27. It is contended that the Petitioner have complied with the standards defined under D&C Act by appointing an approved manufacturing Chemist, responsible for manufacturing; an approved analytical Chemist, responsible for testing of the drugs; qualified QA personnel apart from the responsible person for day-to-day working and conduct of business activities. The Drug was properly tested and the Test Report of the raw material and finished goods, were also enclosed.

28. As per the guidelines of CDSCO, the test for *Extractable Volume falls under the Category-C*, which is a minor fault and is liable for departmental action only. In addition, the manufacturer and the manufacturing activities *were not within the jurisdiction of the Drug Inspector*. Therefore, the Petitioner could not have been prosecuted by the Complainant and it was

only Court which could invoke Section 32A during trial, if the Dealer proved all the conditions under Section 19(3) (a) to (c) of the D&C Act.

29. The Petitioner has asserted that the Summoning Order dated 07.12.2015 has been passed without considering these aspects and therefore, ***the impugned Summoning Order dated 07.12.2015 is liable to be dismissed.***

30. Reliance has been placed on *Municipal Corporation of Delhi Vs. Ghisa Ram* AIR 1967 SC 970, *State of Haryana Vs. Unique Farmaid (P) Ltd. And Others* (1999) 8 SCC 190 and *Medicament Biotech Limited and Another Vs. Rubina Bose, Drug Inspector* (2008) 7 SCC 196.

31. Further objection is taken that the ***Complaint has been filed by Union of India through Drug Inspector.*** The Drug Inspector is not the Complainant. He also cannot represent Union of India because it can be represented only by the Secretary of the concerned Department of the Central Government. For this reason also, the Complaint dated 10.08.2015 is not maintainable and is liable to the rejected.

32. Further, if Union of India is the Complainant, then there is no exemption for Union of India under Section 200 Cr.P.C. from examination. Under Section 200 Cr.P.C, a Magistrate taking cognizance of an offence on Complaints mandatorily required to examine the Complainant and the witnesses present, if any, on oath, and the substance of such examination has to be reduced in writing and signed by the complainant and the witnesses as well as by the Magistrate. The only exemption given ***as per the proviso to Section 200 Cr.P.C.***, is if a Public Servant acting or purporting to act in discharge of his official duties or a Court, has made the Complaint. The

Complaint not being filed by a public servant, the examination of the complainant and the witnesses under Section 200 Cr.P.C., was mandatory.

33. It is further asserted that there was no justification for exempting the Complainant, Drug Inspector from examination under Section 200 Cr.P.C. Such dispensation has been done without there being any such prayer in the Complaint dated 10.08.2015. The Ld. Trial Court has failed to conduct an inquiry under Section 202(1) Cr.P.C despite the fact that the Petitioner/Accused are residing at a place beyond the area in which the Court exercises its jurisdiction. The inquiry under Section 202(1) Cr.P.C. is mandatory if the Court wants to initiate prosecution against an accused who is residing beyond the jurisdiction of the Court. No such inquiry has been conducted by the Ld. MM before taking cognizance and summoning the Petitioner.

34. The summons have been issued without recording the statement of the Complainant, Drug Inspector and without giving any reasons or any kind of satisfaction, which is against the law.

35. It is also contended that *Sh. Rajeev Mukul, Accused No.2, has also been summoned as one of the partners of the Petitioner Firm, despite there being on record, documents to show that he was not involved in day-to-day affairs of the Firm and appointment of a responsible person under the D&C Act.* The Respondent no.2/Complainant, Drug Inspector was well aware about the constitution of the Firm and had also collected the documents in regard to the responsible person for day-to-day working and conduct of business, in compliance of Section 34 of D&C Act and the Complainant has

intentionally arrayed all the partners of the Firm as accused, in the Complaints.

36. There are no specific averments against the partners of the Firm and in the absence thereof, the Complainant has to establish extent of liability against the partners in terms of Section 34 of the D&C Act. The Complaint dated 10.08.2015 does not disclose the necessary facts to make him liable as there must be clear, unambiguous and specific allegations against the persons who are impleaded as accused for which reliance has been placed on *State of Haryana V/s Brij Lal Mittal***,** AIR 1998 SC 2327 and *Vijay Chowdhary Vs State***,** 561-A, CrP.C. No. 44/2003 decided on 23.04.2009**.**

37. The Complaints ***were filed with inordinate delay as the Complaint was filed on 10.08.2015 for both batches of samples*** and no explanation is forthcoming as to why the Complaint has been filed after more than one and a half years of obtaining Report from the Government Analyst.

38. In the end, it is contended that on the face of it, no offence is made out against the Petitioner and *the Summoning Order dated 07.12.2015 in Criminal Complaint No.15/4 of 2015 and CC No. 16/4 of 2015, be set aside and* be quashed.

39. ***Respondents No.1&2 in their Counter Affidavit have submitted*** that Central Drugs Standard Control Organization, Hqrs. (CDSCO) received a request from the Directorate of Health Services, Central Procurement Agency, Swasthya Sewa Nideshalaya Bhawan, F-17, Karkardooma, New Delhi on 18.09.2013 regarding the supply *of sub-standard quality drug KETZY EYE DROPS Batch No. EEZ652 & KETZY EYE DROPS 5ml Batch No. EEZ651 and EEZ653, manufactured by the Petitioner*.

40. In response to CDSCO, it deputed the Respondent No.2, Drug Inspector to draw samples of the Eye Drop from Guru Gobind Singh Government Hospital, Raghubir Nagar, New Delhi, vide letter dated 24.09.2013. Inspection was accordingly carried out and the sample of the drugs of the Eye Drop were taken on 26.09.2013 from Guru Gobind Singh Government Hospital, Raghubir Nagar, New Delhi and Form 17 and 17A were duly filled and handed over to the Medical In-Charge of the Hospital. The sample was sent to Central Drugs Laboratory, Kolkata and the Letter was received for detailed information which was collected and forwarded to the Central Drugs Laboratory, Kolkata.

41. *The Test Report of the sample of batch No. EEZ652* was received vide Letter dated 27.12.2013 with the observation that the sample was ***not of standard quality***.

42. *The Test Report of the other two samples of Batch No. EEZ651 and EEZ653* were received on 03.02.2014. On 10.02.2014, Show Cause Notice along with one sealed sample portion of each batch, were issued upon the Petitioner.

43. The procedure was duly followed and Show Cause Notice under Section 18B of D&C Act dated 09.01.2014 was duly sent to the Petitioner.

44. It is further submitted that the Petitioner did not challenge the Test result under Section 25(3) of D&C Act and merely responded vide its Letter received in the Department on 25.02.2014 that the sample lying with them met with the specification.

45. Section 25(3) categorically states that the challenge has to be made within 28 days from the date of receipt of the Report. However, the

Petitioner have cleverly not mentioned the date of communication to the Respondent No.2, Drug Inspector nor has it mentioned in their Letter when they had received the letter containing the Test Report from the Complainant, Drug Inspector. It is evident that the Petitioner have deliberately concealed the dates.

46. It is submitted that the Petitioner have failed to challenge the report of the Government Analyst, Central Drug Laboratory within the stipulated period of 28 days from the date of receipt of the copy of the said Report and also did not submit any document. It is further submitted that the Petitioner is misleading that the Form 17 does not mention the storage condition; rather it is only about the intimation from whom the sample was taken.

47. It is submitted on behalf of the Respondent No.2, Drugs Inspector that the Petitioner had not submitted any Reply to the Show Cause Notice dated 10.02.2014 and no such letter dated 25.02.2014 was received by the Respondent No.2, Drug Inspector.

48. It is further submitted that the Petitioner has also annexed a letter dated 13.05.2014 in which it has been mentioned that they have received the Show Cause Notice on 26.02.2014. Therefore, it is apparent that the alleged Letter dated 25.02.2014 is a forged document prepared by the Petitioner afterwards.

49. The Petitioner Firm had not submitted the certified copy of the Firm constitution details and other particulars including the competent persons, analytical chemist/competent technical person responsible for production activities and analytical activities respectively.

50. It is further explained that the Petitioner's Manufacturing Unit is in the jurisdiction of Drugs Controlling Licensing Authority Himachal Pradesh. Hence, the Drugs Controller General (I) Hqrs. had sent a letter dated 13.01.2014 & 10.02.2014 to State Licensing Authority, Himachal Pradesh to take necessary action under the Drugs and Cosmetics Act.

51. Furthermore, the Assistant Drug Controller-cum-Drug Licensing Authority vide Letter dated 12.05.2014 only suspended the permission of manufacture of product for 90 days under Rule 85(2) of D&C Rules, but the action taken was not sufficient and proper. As per D&C Act, necessary permission for launching the prosecution was accorded on 13.06.2014.

52. It is submitted that the Criminal Complaint has been filed by the Respondent No.2, Drug Inspector before the Competent Court on 10.08.2015 and summons dated 07.12.2015 have been rightly issued on against the Petitioner.

53. *It is therefore submitted that there is no merit in the present Petition which is liable to be dismissed.*

54. Written submissions have been filed on behalf of the Petitioner as well as the Respondents, essentially reiterating their rival assertions contained in their respective pleadings.

55. **Submissions heard and record perused.**

56. The two Complaints under Section 18(a)(i) read with Section 16 and punishable under Section 27(d) D&C Act has been filed against the Petitioner that the Drug ***KETZY EYE DROPS [Ketorolac Tromethamine Ophthalmic Solution) Batch Nos. EEZ652, EEZ651 & EEZ653***

manufactured by them, were found to be ***not of standard quality*** according to the D&C Act and D&C Rules made thereunder.

Right of Re-testing of samples under Section 25 D&C Act:

57. ***The first contention on which the Petitioner*** have sought the quashing of summoning order dated 07.12.2015, is that the Complaint dated 10.08.2015, both of the same date, was not filed within one month of the receipt of the Testing Report whereby the valuable right under Section 25(3) and (4) to seek re-examination from the Central Testing Laboratory, got defeated. The relevant part of Section 25 reads as under: -

> *"**25. Reports of Government Analysts***
> *…….*
> *(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken 5 [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** 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.*
> *(4) **Unless the sample has already been tested or analysed in the Central Drugs Laboratory,** where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug 3 [or cosmetic] produced before the Magistrate under subsection (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the **Director of the Central Drugs Laboratory** the result thereof,*

and such report shall be conclusive evidence of the facts stated therein."

58. ***Section 25(3)*** provides that the Report of the Government Analyst shall be conclusive unless the person from whom the sample is taken 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 proceedings in respect of the sample are pending, that he intends to adduce evidence in controversion of the Report.

59. ***S. 25(4)*** provides that '***unless the sample has already been tested by the Central Drugs Laboratory'*** and under S.25(3) the person has already notified his intention to adduce the evidence in controversion of the Report of the Government Analyst, the sample lying with the Court be sent for retesting to the Central Drug Laboratory, which shall be conclusive evidence of the fact.

60. The Apex Court in State of *Haryana v. Brij Lal Mittal*, (1998) 5 SCC 343 has observed that;

"*5. From a bare perusal of sub-section (3) it is manifest that the report of the Government Analyst 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 or other particulars have been disclosed under Section 18-A (in this case the manufacturers)* ***has within 28 days of the receipt of the report*** *notified in writing 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. Sub-section (4) also makes it abundantly clear that the right to get the sample tested by the Central Government Laboratory (so as to make its report override the report of the Analyst) through the court accrues to*

> *a person accused in the case only if he had earlier notified in accordance with sub-section (3) his intention of adducing evidence in controversion of the report of the Government Analyst.* ***To put it differently, unless requirement of sub-section (3) is complied with by the person concerned he cannot avail of his right under sub-section (4)****."*

61. Therefore, from the reading of S.25(3) & (4), the Conditions for retesting are:

(i) *The intention of the manufacturer to adduce evidence in contraversion of the report of the Government Analyst with 28 days of receipt of the report; and*

(ii) *The said sample has not been tested by the Central Drugs Laboratory.*

Contraversion of the Report of the Government Analyst with 28 days of Receipt of Report under ***S.25(3):***

62. In the ***first Complaint case,*** the sample of Batch No. EEZ652 was collected on 26.09.2013 and was sent to ***Central Drugs Laboratory, Kolkata*** for testing on the very next day on 27.09.2013. The Report from the Central Drugs Laboratory was received on ***27.12.2013*** (though in this Report the date of Report was mentioned as 27.12.2012 which got corrected on 31.12.2013). Within five days of 31.12.2013, the Report was sent on 06.01.2014, to the Hospital from where the sample was collected and on 09.01.2014, to the Petitioner who were the manufacturers of the drug.

63. The Petitioner gave their Reply to Show Cause Notice dated Nil which was received by Respondent No.2, Drug Inspector on 25.02.2014 stating therein that the sample lying in the possession are *complying the test*

of Extractable Volume & all tests are within the limits and therefore, requested the Respondent No. 2, Drug Inspector to take a lenient view.

64. It is significant that this option to controvert the Report of Central Drugs Laboratory, had to be conveyed to the Inspector or the Court within 28 days of receiving the Show Cause Notice. Reply has been sent on 25.02.2014 which is about 15 days more than the prescribed timeframe of 28 days. ***The Petitioner having failed to submit their option under Section 25(3) within the mandated period of 28 days, cannot now agitate that it had a right to controvert the Report of Central Drugs Laboratory.***

65. Section 25(4) becomes operative only after the compliance of Section 25(3); *since there is no compliance and option had not been given within the statutory period under* Section 25(3), *the right of re-testing under Section 25(4) would not accrue on the Petitioner.*

66. Whereas, in the ***case of second Complaint pertaining to samples of Batch No. EEZ651 & EEZ653 ,*** it is important to state that the Report dated 03.02.2014 were received on 10.02.2014 and immediately Show Cause Notice was issued to the Petitioner. It is the case of the Petitioner that after receiving the said Show Cause Notice, a letter dated 25.02.2014 was issued to the Respondent No.2, Drugs Inspector in controversion of the Test Report. However, the Respondent No.2, Drugs Inspector has denied the receipt of any such Letter dated 25.02.2014 which is a disputed fact required to be proved by the Petitioner at the time of trial. This contention of the Petitioner that he had exercised the right of controversion, cannot be agitated at this stage, in the present Petition.

Section 25(4): *Testing by Central Drugs Laboratory****:***

67. Another aspect which is of immense significance is that ***Section 25(4)*** provides that *unless the sample has already been tested or analysed* ***in the Central Drugs Laboratory,*** the person has a discretion to request the re-testing of the sample. However, in the present case, pertinently the sample had been sent to ***Central Drugs Laboratory, Kolkata which was a Central Testing Laboratory***. Once the testing has been done by the said Central Drugs Laboratory, there was no question of exercising the right and the Petitioner had no option for re-testing under Section 25(4) of Drugs and Cosmetics Act.

68. ***Therefore, the claim of the Petitioner that their valuable right to get the sample re-tested has been defeated, is absolutely in the teeth of specific provisions under Section 25(3) and (4) of the Act and not tenable at this stage of summoning***.

Filing of Complaint after the expiry of the drug:

69. Another contention of the Petitioner connected to Section 25(3) and (4) of the D&C Act was raised that the aforesaid Complaints had been filed on 10.08.2015 i.e. after more than one year and seven months of receipt of the testing report from Central Drugs Laboratory. This belated filing of the Complaint, has defeated their valuable right under Section 25(4) of the Act.

70. However, as has already been discussed above, the delayed filing of the Complaint in August, 2015 even though the Testing Report had been received in December, 2013 and February 2014 respectively, is of little consequence in the light of the above discussion that no such right of re-testing had accrued upon the Petitioner under S.25 (4), in the given circumstances.

71. The Complaint dated 10.08.2015 has been filed within the period of limitation which is three years from the date of lifting the sample. Therefore, as this ground under Section 25 of the D&C Act and delay in filing of the Complaint, does not ensure to the benefit of the Petitioner, ***the summoning Order*** is not liable to be quashed on this ground.

Liability of the Partners of the Manufacturing Firm:

72. ***The second contention that has been raised*** is Rajeev Mukul who is one of the accused person in the Complaint, was not involved in day-to-day affairs of the Firm and as was evident from the documents furnished by the Petitioner and was entitled to be discharged.

73. In the case of *Maksud Saiyed vs. State of Gujarat and Others* (2008) 5 SCC 668 it was observed that while levelling the charges against the Company, it is obligatory on the part of the Complainant to make requisite allegation in the Complaint as to the role of the directors for making him vicariously liable.

74. ***In the present case, though this contention may have some merit, but considering that the present Petition has been filed only by the firm M/s. Zee Laboratories through an authorized representative and not by the Partners, this aspect cannot be considered, but is left open to be considered during the trial***.

Jurisdiction in the case of Complaint when Manufacturing Unit is situated outside:

75. ***The third objection taken is that the Petitioner***, manufacturer was based in Sirmour, Himachal Pradesh and the Complaint could not have been filed in Delhi.

76. In *Ashok Sureshchand Bal v. State of Maharashtra*, 2001 SCC OnLine Bom 822, the Bombay High Court has held;

> " …. *even though the Firm falling in the jurisdiction of the Court from where the samples had been taken had not been party yet one of the purchasers who did not fall within the jurisdiction of the Court, had been a party along with the manufacturer. In my opinion, taking into account the purpose sought to be achieved by the said Act,* ***the principle has to be expanded and wherever an adulterated drug is manufactured, the manufacturer can be prosecuted at the place where the drug is sold irrespective of whether the seller has been made party or not since the consequences ensue at the place where the goods are sold and purchased.*** *The goods are manufactured for the purpose of distribution throughout the country and the manufacturers cannot be permitted to escape their liability on technical grounds.* ***At any rate, the consequences of manufacturer of adulterated drug ensue wherever the drug is sold and as such manufacturer can be sued at any place of sale of adulterated drug.*** *Of course, the sale within the jurisdiction of the Court taking cognizance against the manufacturer will have to be established*.

77. In this light of the aforesaid judgement, even though the Manufacturer was located in Himachal Pradesh, but *drug* was being distributed in Govt Hospital in Delhi from where the sample was collected.

Therefore, the contention that Delhi Courts did not have the territorial jurisdiction, is without merit.

Examination of Public Servant under Cr.P.C. after filing of the Complaint:

78. ***The fourth ground that has been agitated on behalf of the Petitioner*** is that though the Complaint dated 10.08.2015 had been filed by the Respondent No.2, Drug Inspector but due procedure under Section 200

Cr.P.C. was not followed by the Ld. MM before summoning the Petitioner and on this ground the summoning Order is liable to be quashed.

79. The **first Proviso** to Section 200 Cr.P.C. reads as under:

> *Provided that, when the complaint is made in writing, the Magistrate need not examine the complainant and the witnesses.*
>
> *(a) If a public servant acting or purporting to act in the discharge of his official duties or a court has made the complaint; or*

80. The **first Proviso** to Section 200 Cr.P.C., thus, provides that the ***Magistrate need not examine the complainant*** if a public servant acting or purporting to act in the discharge of his official duties or a Court has made the Complaint in writing.

81. The Complaint dated 10.08.2015 has been lodged by Respondent No.2, Drug Inspector, Shri Dharmvir Singh who has been duly authorised vide Notification bearing No. DVS/DI/HQ/2013/14 dated 13.06.2014 to initiate the prosecution against the Petitioner. Therefore, under the ***Proviso to Section 200 Cr.P.C.***, the Ld. MM rightly exempted the Complainant, Drug Inspector and his witnesses from examination, before taking cognizance of the offence on the Complaint.

82. This aspect was considered in detail by the Apex Court in the case of *Cheminova India Limited v. State of Punjab*, 2021 SCC OnLine SC 573 wherein similar objection was taken. It was observed that *the legislature in its wisdom, has placed on the public servant on a different pedestal, as is evident from the proviso to Section 200 Cr.P.C. and the object of holding an inquiry/ investigation before taking cognizance, in cases where accused resides outside the territorial jurisdiction of such Magistrate, is to ensure*

that innocent persons are not harassed unnecessarily. By virtue of proviso to Section 200 Cr.P.C., the Magistrate, while taking cognizance, need not record statement of such public servant, who has filed the complaint in discharge of his official duty. Further, by virtue of Section 293 of Cr. P.C., report of the Government Scientific Expert is, per se, admissible in evidence. The Code of Criminal Procedure itself provides for exemption from examination of such witnesses, when the complaint is filed by a public servant. Since the Complaint filed by Public Servant under the provisions of the Insecticides Act, 1968, enclosing several documents including reports of the Government Laboratories, it was observed that this submission did not have any merit and the proceedings were not liable to be quashed on this ground itself. In the absence of showing any prejudice caused to the appellant at this stage, it was held to be no ground for quashing of the proceedings in exercise of power under Section 482 Cr.P.C.

83. In the present case as well, the facts involved are *para materia*. It also cannot be overlooked that the Sample was taken form Govt. Hospital in Delhi and part cause of action has arisen in Delhi. ***Therefore, it cannot be considered to be a ground for quashing of the impugned summoning Order.***

Conclusion:

84. In view of the aforesaid discussion, no grounds are made out for quashing of the Summoning Order dated 07.12.2015 in *Criminal Complaint No.15/4 of 2015 and 16/4 of 2015*. However, observations made herein do not tantamount to an expression on merits which may be considered in the light of evidence led by both the parties.

85. The present Petition is hereby, dismissed and the pending Application(s) are disposed of accordingly.

(NEENA BANSAL KRISHNA)
JUDGE

JUNE 27, 2025/*pp*