R

IN THE HIGH COURT OF KARNATAKA AT BENGALURU

DATED THIS THE 30TH DAY OF AUGUST, 2024

BEFORE

THE HON'BLE MR JUSTICE N S SANJAY GOWDA

CRIMINAL PETITION NO. 8341 OF 2018

BETWEEN:

1. M/S ZIM LABORATORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWAR-441501
DISTRICT NAGPUR,
MAHARASHTRA.

REPRESENTED BY ITS
MANAGING DIRECTOR,
MR. ANWAR SIRAJ DAUD AND
CHAIRMAN,
ZAKIRABHAI SULEHBHAI VALI

2. MR. ZAKIRBHAI SALEHBHAI VALI,
AGED ABOUT 76 YEARS,
S/O MR.SALEHBHAI ABDULALI VALI,
CHAIRMAN OF
M/S ZIM LABORATIORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWAR-44 1501.
DISTRICT NAGPUR,
MAHARASHTRA.

3. MR. ANWAR SIRAJ DAUD
AGED ABOUT 55 YEARS,
S/O MR. SIRAJ MEHFUZ DAUD,
MANAGING DIRECTOR OF
M/S ZIM LABORATORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWAR-441 501.
DISTRICT NAGPUR,
MAHARASHTRA.

4. MR. RIYAZ AHMED KIKABHAI KAMAL
AGED ABOUT 64 YEARS,
S/O MR. KIKABHAI TAHERALI KAMAL,
EXECUTIVE DIRECTOR OF
M/S ZIM LABORATORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWAR-441 501.
DISTRICT NAGPUR,
MAHARASHTRA.

5. MR. NITIN RAJENDRA PUDKE,
AGED ABOUT 56 YEARS,
MANUFACTURING CHEMIST OF
M/S ZIM LABORATORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWAR-441 501.
DISTRICT NAGPUR,
MAHARASHTRA.

6. MR. AMOL SURESH KAKDE,
AGED ABOUT 52 YEARS,
MANUFACTURING CHEMIST OF
M/S ZIM LABORATIORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWR-441 501.
DISTRICT NAGPUR,
MAHARASHTRA.

7. MRS.MANJUSHA SHIVCHARAN MESHRAM,
AGED ABOUT 48 YEARS,
MANUFACTURING CHEMIST OF
M/S ZIM LABORATORIES LTD.,
B-21/22, MIDC AREA,
KALMESHWAR-441 501.
DISTRICT NAGPUR,
MAHARASHTRA.

…PETITIONERS

(BY SRI. DESU REDDY.G., ADVOCATE)

AND:

1. UNION OF INDIA,
   MINISTRY OF HEALTH AND FAMILY WELFAR
   O/O THE CENTRAL DRUGS STANDARD
   CONTROL ORGANISATION,
   DIRECTORATE GENERAL OF HEALTH SERVICES
   O/O OF ASSISTANT DRUGS CONTROLLER(I)
   2ND FLOOR, O/O DRUGS CONTROLLER
   FOR THE STATE OF KARNATAKA, PALACE ROAD,
   BENGALURU-560 001.

   REPRESENTED BY
   CENTRAL GOVERNMENT PUBLIC PROSECUTOR,
   HIGH COURT BUILDING,
   AMBEDKAR VEEDHI,
   BENGALURU-560 001.

…RESPONDENT

(BY SRI. MADHUKAR DESHPANDE, SENIOR CGSC)

THIS CRIMINAL PETITION IS FILED UNDER SECTION 482 CR.P.C BY THE ADVOCATE FOR THE PETITIONER PRAYING THAT THIS HON'BLE COURT MAY BE PLEASED TO QUASH THE ENTIRE PROCEEDINGS IN C.C.No.273/2016 ON THE FILE OF THE LEARNED PRESIDING OFFICER, SPECIAL COURT FOR ECONOMIC OFFENCES AT BANGALORE.

THIS PETITION HAVING BEEN HEARD AND RESERVED FOR ORDERS ON 26.06.2024, COMING ON FOR PRONOUNCEMENT THIS DAY, THE COURT MADE THE FOLLOWING:

CORAM: HON'BLE MR JUSTICE N S SANJAY GOWDA

CAV ORDER

1. This criminal petition is filed opposing the criminal proceedings initiated against the petitioners — for the offence punishable under Section 27D of the Drugs and Cosmetics Act, 1940 ("**the Act**") — in Criminal Case No.273 of 2016, relatable to the subject samples of a drug called "*Regunac Na^{+} SR 100 (Slow Diclofenac Tablets B.P. 100 mg)"* [referred to as "***Regunac***" or "***the drug sample"*** or "***the subject drug***"] which was termed as being – "***Not of Standard Quality (NSQ)***".

2. For ease of reference, this order has been indexed as follows:

Sl. No.	Particulars	Page Nos.
I.	Brief facts	05
	A. Re: 1st sample [Batch No.F957 G220]	05
	B. Re: 2nd sample [Batch No.F957 C404]	11
II.	Counsels' submissions	19
III.	Overview of the Act and the Rules	22
IV.	Application of the law to the facts of this case	43
V.	Conclusion	68
VI.	Directions	69

I. BRIEF FACTS:

3. The facts leading to the filing of this petition, in respect of the two samples in question, are as under:

A. RE: First Sample [Batch No.F957 G220]:

(a) On 28.02.2013, the Drugs Inspector (India), Central Drugs Standard Control Organization (CDSCO), Sub-Zone Office of the Drugs Controller for State of Karnataka, Bengaluru, ("**the Drugs Inspector**") took the samples of the subject drug–Regunac from the Employees' State Insurance ("**ESI**") Hospital in Mangalore. This drug was manufactured under Batch No.F957 G220.

(b) The date of manufacture of the subject drug was July, 2012 and the date of its expiry was June, 2015.

(c) The Drugs Inspector divided the sample into four equal parts, out of which he gave one portion to the Pharmacist of the said ESI Hospital and sent another portion of the sample to the Director, Central Drugs Laboratory, Kolkota ("**the CDL**"), i.e., the Government

Analyst. This sample was sent to the Government Analyst on 04.03.2013.

(d) On 11.03.2013, the drug sample was received by the Government Analyst for test/analysis, as contemplated under Section 23(4) of the Act. Though the Government Analyst received the drug sample on 11.03.2013, the test was conducted only between 10.11.2014 and 12.11.2014, i.e., nearly 20 months after the drug sample was received.

(e) About six months thereafter, the Government Analyst furnished the Test Report in triplicate to the Drugs Inspector by his Memorandum dated 05.05.2015. In this Certificate of test/analysis, he stated that the sample given to him did not pass the "Drug Release Test" and he concluded that the sample was "**not of standard quality**".

(f) The Drugs Inspector, thereafter, by his letter dated 14.05.2015, called upon the Pharmacist of the ESI Hospital, Mangalore (from whom he had secured the drug

samples) to furnish the name and address of the person from whom he had acquired the subject drug along with a copy of the invoice and the quantity received, while informing the Pharmacist that the drug sample that he had collected did not conform to the test for drug release and, therefore, he declared the drug sample as "**not of standard quality**".

(g) He also alerted the Drugs Controller, Karnataka on the movements of the drug and for initiation of action as provided under the provisions of the Act.

(h) The notice was re-sent to the Medical Superintendent / Pharmacist, ESI Hospital, Mangalore on 18.05.2015 since the Pharmacist to whom the earlier notice had been addressed had been transferred.

(i) On 23.05.2015, the Pharmacist informed the Drugs Inspector that the ESI Hospital, Mangalore had secured the drug directly from M/s. Zim Laboratories Limited, Nagpur, Maharashtra i.e., petitioner No.1 under the

invoice dated 28.09.2012, a copy of which was also enclosed.

(j) On 09.06.2015, the Drugs Inspector addressed a letter to petitioner No.1 informing them that the drug sample was declared to be "**not of standard quality**", since the sample did not conform to the parameters of the test for drug release. A copy of this test report and a portion of the sealed sample were also forwarded to petitioner No.1, who was also called upon to stop the sales and distribution of the subject and withdraw stock from the market immediately. A direction was also issued to submit certified copies of twelve documents mentioned therein.

(k) Petitioner No.1 responded by a letter dated 16.06.2015 stating that they had been manufacturing the subject drug for the past 15 years and they had not received any complaint about it till date. It was also stated that on a scrutiny of the Government Analyst's report, it was observed that the sample of the subject batch was

received on 11.03.2013 and it was tested between 10.11.2014 and 12.11.2014, which indicated that the drug sample had been kept for 20 months in the Laboratory. It was stated that since the subjected product is a *'sustained release formulation'*, the storage condition could alter the physio-chemical attributes of the drug. It was also stated that steps had been taken to recall and stop the distribution of the available stock of the subjected drug from the market and also from ESI Hospital, Mangalore, pending their investigation and further line of action. It was also stated that the analysis of the portion of the sample that had been sent to them was under progress, and that after analysis, the details of the results and the further line of action would be shared with the Department. Certain documents, which were sought by the Drugs Inspector, were also forwarded to the Drugs Inspector including the declaration that they were the manufacturers of the subject drug.

(l) On 23.06.2015, petitioner No.1 addressed a letter to the Drugs Inspector stating that it had analyzed the sample that it had received from her, and as per the analysis of the subject product for the test of drug release in their Quality Control laboratory, the results obtained indicated that the subject drugs were well within the accepted criteria and it was clear that the product batch complied with the test for drug release. It was therefore stated by petitioner No.1 that it did not agree with the report of the Government Analyst, by which the subject drug had been declared as '**not of standard quality**' and they also stated that they would like to challenge the report of the Government Analyst. A request was also made to send a portion of sample of their product to the CDL, Kolkata for analysis of the drug release only as per the analysis enclosed therewith. Petitioner No.1 also sought the details of the Court / Magistrate and also the amount of demand draft and details to whom it should be made out to. Petitioner No.1 further submitted the analytical results for drug release of the portion of sample

of the subject batch product along with the method of analysis.

(m) The Assistant Drugs Controller, CDSCO, Bangalore by a letter dated 06.07.2015 requested the Deputy Drugs Controller (India), CDSCO, West Zone, Mumbai to get the matter investigated at the Manufacturer's unit and submit the investigation report, since the drug sample had failed the test for drug release and was declared as '**not of standard quality**'. The Certificate of Test/Analysis (Form No.13) was also furnished to the Drugs Controller.

B. RE: Second Sample [Batch No.F957 C404]:

(n) On 12.06.2014, the Drugs Inspector, collected another sample of the same drug bearing Batch No.F957 C404 from the premises of the Regional Drug Store, ESI Directorate, Rajajinagar, Bangalore. He divided the sample into four equal portions and handed over one portion of the drug sample to the Senior Insurance Medical Officer of the Regional Drug Store, ESI Directorate, Rajajinagar, while another portion of the drug sample was sent to the

Director, Central Drugs Laboratory, Government of India, Kolkata.

(o) The Government Analyst, though received the drug sample on 17.06.2014, subjected the sample for testing five months thereafter — between 10.11.2014 and 12.11.2014.

(p) After eight months, i.e., on 15.07.2015, the Government Analyst concluded that the drug did not pass the test relating to drug release and declared the sample as '**not of standard quality**' by his report dated 15.07.2015.

(q) The Drugs Inspector, immediately thereafter, on 20.07.2015, called upon the Senior Insurance Medical Officer, Regional Drug Store, ESI Directorate, Rajajinagar, Bangalore (from where she had collected the samples) to furnish the name and address of the person from whom it had acquired the subject drug, along with a copy of the invoice and the quantity received. She informed the

Medical Officer about the drug sample being sent for test/analysis and the report that she had received regarding the drug being '**not of standard quality**'. The Drugs Inspector also alerted about the movement of the subject drug and that necessary action should also be initiated as per the provisions of the Act.

(r) This notice asking for information was re-sent on 31.07.2015, since the Medical Officer to whom the earlier notice had been addressed was transferred and that said notice had been returned.

(s) In response, the Junior Specialist, Regional Drug Store, ESI Directorate, Rajajinagar, Bangalore, by his letter dated 03.08.2015, informed the Drugs Inspector that the subject drug was manufactured by M/s. Zim Laboratories Limited–petitioner No.1 herein and also enclosed a copy of the invoice under which the subject drug was procured. It was further stated that they had also received 13,860 tablets of the subject drug from the aforesaid manufacturer and at present, there was no stock

of the subject drug and that they would send a recall intimation to all the dispensaries (to whom it had supplied the subject drug) to stop using the subject drug immediately.

(t) On receipt of said letter, on the same day, i.e., on 03.08.2015, the Drugs Inspector addressed a letter to petitioner No.1 stating that the drug sample was declared to be '**not of standard quality**' since the drug sample did not conform to the test for drug release. A copy of the test report and one portion of the sealed drug sample were also sent to petitioner No.1 and a direction was issued to it to stop the sale and distribution of the subject drug and withdraw the stock from the market immediately. In addition, thirteen documents were sought.

(u) On the same day, a letter was addressed to the Deputy Drugs Control (India), CDSCO, West Zone, Mumbai calling upon them to conduct an investigation regarding the subject drug, in view of the report received at the 1st

petitioner's unit, and submit a report along with the details, so as to launch a case against petitioner No.1.

(v) In response to the notice dated 03.08.2015, petitioner No.1 issued a reply dated 10.08.2015, in which it was stated that no stock of the subject batch of drug was available with them and that they had initiated action for the immediate recall of and stopping the distribution of the available stock of the subject batch from the market. It was also stated that the received portion of the sample was under analysis and the details of the results and the relevant documents along with their further line of action would be communicated to them.

(w) On 26.08.2015, petitioner No.1 addressed another letter wherein it was stated that the controlled sample was analyzed, and the controlled samples as well as a portion of the sample of the subject batch as per the method of analysis of the product for the test of drug release in their Quality Control laboratory and the control sample of the subject batch complied with the test for drug release

within the specified criteria and in respect of the received portion sample, it had passed the test for drug release at L2 stage, as per British Pharmacopeia for interpretation of drug release. A copy of the analytical results of the control sample and the portion sample was also enclosed. It was also stated that the drug release time points and the percentage of drug release was not specified in the British Pharmacopeia.

(x) It was also stated that a joint investigation had been carried out by the Drugs Inspector, CDSCO, West Zone, Mumbai on 13.08.2015 wherein a thorough investigation had been done by the Drugs Inspector, FDA, Nagpur Division, during which petitioner No.1 had furnished nine documents. Petitioner No.1 also furnished six other documents to the Drugs Inspector for taking appropriate action.

(y) It may be pertinent to state here that a joint investigation conducted on 13.08.2015 was in respect of the first sample (Batch No.F957 G220) and the investigation

report had been forwarded to the Deputy Drugs Controller (India), Drugs Controller for the State of Karnataka, Bangalore along with a covering letter dated 21.10.2015, and this joint investigation report had concluded that the firm had analysed the finished product (before batch release for sales /distribution) and it had found that the drug release test complied with the manufacturer's specifications and that the same had also been verified. It was also remarked that the drug release test of the investigational product had been performed as per the manufacturer's specifications and the results in the finished product analysis report were compliant with the standards prescribed. It was further remarked that petitioner No.1 had stated that the product complied with their shelf-life specification, which was effective from 22.01.2015, but the product found to be '**not of standard quality**' with respect to the test for 'drug release' had been manufactured before the said date.

(z) About two months thereafter, on 06.11.2015, the Drugs Inspector sought additional documents for both these batches of two samples relating to the Managing Directors, Directors and Partners at the time of offence i.e., July of 2012 and March of 2014, and the person(s) in charge of and responsible for the Company's business at the time of offence, along with their name, identification and address proof of the manufacturing chemist and analytical chemist responsible for manufacturing the subject drug during July, 2012 and March, 2014, and also sought information on the process validation and cleaning validation documents of the subject drug.

(aa) On the same day, a letter was addressed to the Drugs Controller General (India), CDSCO, New Delhi seeking permission to launch prosecution against petitioner No.1—Company.

(bb) Petitioner No.1 complied with the demand for production of additional documents by their letter dated 23.11.2015.

(cc) On 04.12.2015, the Drugs Controller General (India) granted approval for launching of prosecution against petitioner No.1 firm/person(s) for the violation of the provisions of the Act.

(dd) Thereafter, the Drugs Inspector sought additional documents not only from petitioner No.1, but also from the Registrar of Companies.

(ee) Ultimately, on 22.09.2016, the Drugs Inspector proceeded to present the complaint (dated 24.08.2016) under Section 200 of the Criminal Procedure Code, 1973 ("**the CrPC**") for offence punishable under Section 27(d) of the Act for the manufacture of two batches of drugs, which were '**not of standard quality**'.

As stated above, this criminal petition is filed challenging the initiation of these proceedings.

II. COUNSELS' SUBMISSIONS:

4. Mr. Desu Reddy G.—learned counsel for the petitioners as well as Mr. Madhukar Deshpande—learned

Central Government Standing Counsel (CGSC) for the respondent made elaborate submissions in support of their contentions.

5. The learned counsel for the petitioners contended that the proceedings were liable to be quashed for the following reasons:

(i) No proceedings could have been initiated against petitioner No.1—Company, its Chairman, its Managing Director and its Executive Director when the complaint itself did not contain any specific averments against them regarding their involvement in the manufacture of the subject drug.

(ii) The entire proceedings were vitiated since the procedure prescribed under the Act and the Drugs and Cosmetics Rules, 1945 ("**the Rules**") had been flouted and the tests were conducted after the shelf-life of the sample drugs had expired and, hence, their results would not indicate that the subject drugs were '**not of standard quality**'.

(iii) A portion of the samples were furnished to them along with the test report after their shelf-life had expired and, hence, petitioner No.1—Company had lost its statutory right to challenge the test reports.

6. The learned CGSC appearing for the Union—Mr. Madhukar Deshpande supported the case of the prosecution and put forth these contentions:

(i) The prosecution had been launched on the petitioners after duly verifying their culpability in the crimes which were ascertained during the course of investigation conducted in accordance with the provisions of the Act and the Rules and, hence, they were justified.

(ii) It would not be necessary to specifically aver the involvement of the persons in charge of the conduct of business of the Company and the persons involved in the manufacturing of the subject drug, since it had been stated that all of the accused were responsible, and also because the entire papers relating to the

investigation were placed before the Court/Magistrate and these papers, by themselves, indicated their involvement which the Magistrate would peruse.

(iii) The test reports obtained clearly indicated that the drugs were '**not of standard quality**' and all the petitioners were thus required to be prosecuted.

III. OVERVIEW OF THE ACT AND THE RULES:

7. In order to appreciate these contentions, a brief overview of the provisions of the Act and the Rules which were enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics would be necessary.

8. The Act has been divided into five chapters. For the purpose of this case, the provisions of Chapter IV and some provisions of Chapter V would be relevant.

9. Chapter IV relates to the manufacture, sale and distribution of drugs and cosmetics. Section 16 deals with

"**standard of quality**" and states that said expression in relation to a drug would mean that said drug complies with the standard set out in the second schedule. This chapter also seeks to define 'misbranded drugs' (Section 17); 'adulterated drugs' (Section 17A); 'spurious drugs' (Section 17B) which would, however, not be relevant for this case.

10. Section 18 of the Act prohibits the manufacture and sale of certain drugs and cosmetics. It declares that no person should, either by himself or through any other person, manufacture for sale or for distribution, or sell, or stock or exhibit or offer to sell, or distribute any drug which is not of standard quality, or is misbranded, adulterated or spurious [Section 18(a)(i)].

11. Section 18A of the Act casts a legal obligation on every person to disclose to the Inspector — the name, address and other particulars of the person from whom he acquired the drug or cosmetics.

12. Section 20 of the Act provides for the State Government (and also the Central Government) by notification in the Gazette to appoint such persons as it thinks fit and who possess the prescribed qualifications to be Government Analysts in respect of such drugs or classes of drugs.

13. Section 21 of the Act similarly provides for the Central Government or the State Government to appoint Inspectors who possess the prescribed qualifications.

14. Section 22 of the Act deals with the powers of the Inspectors so appointed and this Section declares that the Drugs Inspectors shall have the power to investigate, take samples of any drugs, and also search any person, enter and search any place, as well as stop and search any vehicle — if he has reason to believe that an offence in this chapter had been/was being committed. This Section also empowers him to examine any record, register, document or any other material object found and also require any person to produce any record or register, etc.

15. Section 23 of the Act prescribes the procedure to be followed by the Inspectors. It states that if an Inspector decides to take any sample of a drug, he should tender a fair price for it and may also ask for a written acknowledgement [Section 23(1)] in that regard.

16. Section 23(3) of the Act, which is relevant for the case at hand, states that whenever an Inspector takes a sample of a drug for the purpose of test or analysis, he should intimate such purpose, in writing, and in the prescribed form, to the person from whom he takes the sample and, he should thereafter, in the presence of such person, divide the sample into four portions and effectively seal and suitably mark the same. He is also required to permit the person, from whom the sample was taken, to add his own seal and mark. If, however, the sample of drug is taken from the premises of a manufacturer, he is required to divide it into only three portions.

17. The Drugs Inspector under Section 23(4) of the Act is required to give out one of the four portions of the

sample drug i.e., the 1st portion of the drug sample to the person from whom he has taken it, and he is thereafter required to send one portion i.e., the second portion, forthwith to the Government Analyst for test or analysis.

18. He is also required to produce the 3rd portion in the Court before which proceedings have been initiated in respect of the drug or cosmetic.

19. The Inspector is also required send the 4th portion to the person whose name, address and particulars have been disclosed to him under Section 18A i.e., the person from whom the drug had been acquired.

20. Thus, the first thing that an Inspector is required to do, on taking a sample of a drug for test or analysis, is that he should make 4 portions of it and furnish it to the person from whom it has been secured and, at the same time, to the Government Analyst for test or analysis. This is obviously because there is a need to first ascertain the

quality of the drug, and this ascertainment is to be done — not by him but by a notified Government Analyst.

21. It is to be noticed here that Section 23 (4)(i)[1] uses the expression "*forthwith for test or analysis*" and it is therefore imperative that the sample of the drug should be dispatched to the Government Analyst immediately without any delay. The logic behind this imperative is clear that the law intends that the quality of the drug sample should be tested or analyzed immediately, as the circulation or use of the drug whose quality is suspect would lead to grave and dangerous consequences to the public at large.

22. At the stage of taking the sample, obviously, the Inspector would not be aware of the person from whom the drug was acquired, and he would therefore have to take steps to ascertain the person from whom the drug

[1] (4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

had been acquired, as provided under Section 18A. It is only after he ascertains this fact is he required to send the fourth portion to the person from whom the drug was acquired.

23. Since the legislature has made it imperative for the Inspector to secure a test/analysis of the drug sample forthwith, it would also be the requirement of the law that the Inspector takes simultaneous action to ascertain from whom the drug was acquired. This would also be because, the moment he is informed of the results of the test or analysis by the Government Analyst, he can proceed against the person from whom the drug had been acquired.

24. The requirement of producing the third portion to the Court would not be an immediate requirement, unless, of course, there are already proceedings pending before a Court regarding said drug. This is also because the Inspector cannot proceed to prosecute the manufacturer

or any other person responsible for the drug unless it has been tested and analysed by the Government Analyst.

25. Section 24 of the Act also casts an obligation on every person, who is in charge of the any premises where the drug is manufactured or kept for sale or for distribution, to disclose to the Inspector the place where the drug is manufactured.

26. Section 25 of the Act[2] deals with the reports of the Government Analysts. Section 25(1) of the Act mandates

[2] **25. Reports of Government Analysts**.—(1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter 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 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.

that the Government Analyst, to whom a sample of any drug is sent for test or analysis, should deliver to the Inspector a signed report in triplicate in the prescribed form.

27. At this stage, a reference to the '*duties of Government Analysts*' as prescribed under the Rules as it originally stood before its amendment and after its amendment in 2017 would also have to be made.

28. Rule 45 of the said Rules, as it stood before the amendment, stated as follows:

> "**45. Duties of Government Analysts.–** (1) The Government Analyst shall cause to be analysed or tested such samples or drugs and cosmetics as may be sent to

---

(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 or cosmetic produced before the Magistrate under sub-section (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.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

him by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these Rules.

(2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government."

29. Prior to the amendment of 2017, Rule 45 stipulated that a Government Analyst should cause to be analyzed or tested such samples sent to him by the Inspector and should also furnish the report of the results of the analysis in accordance with the Rules. Rule 46 stipulated that immediately after the test or analysis was made, he was required to supply the report *forthwith* to the Inspector. Thus, the Rules, by the use of the word "*forthwith*" also made it clear that the Government Analyst was required to act with promptitude in the matter of conducting the test and also in furnishing the report to the Inspector.

30. Following the 2017 Amendment, Rule 45 reads as follows:

> "**45. Duties of Government Analysts.—** (1) The Government Analyst shall cause to be analyzed or tested such samples of drugs and cosmetics as may be sent to him by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these rules ***within a period of sixty days*** of the receipt of the sample:
>
> Provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving specific reasons for delay in such testing or analysis.
>
> (2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government."
>
> (*emphasis supplied*)

31. Rule 45, after the amendment, has gone one step further and has made it mandatory for the Government Analyst to conduct the test / analysis and also send the

report to the Inspector "*within a period of sixty days*" from the receipt of the sample. In the event the Government Analyst is unable to conduct the test or analyse the sample and send the report within sixty days, he is bound to seek extension of time from the Government, giving specific reasons.

32. The intent of this Rule both before and after the amendment is rather simple and clear. It is the mandate of the law that a Government Analyst is required to conduct the test of a sample and also send a signed report in triplicate at the earliest. In fact, after the amendment, a period of two months from the receipt of the sample is prescribed for conducting the test and for sending the report. This time period stipulated is obviously to ensure that further action regarding the manufacture/sale of drug is taken immediately by the Inspector.

33. The use of the expression "*shall forthwith send to the Government Analyst*" used in Section 23 of the Act and the stipulation of conducting the test and sending the signed

reports forthwith under the old Rule and within a period of sixty days under the amended Rule leaves no shadow of doubt that the entire process of taking the sample and analyzing the same is to be done as expeditiously as possible.

34. The Inspector is thereafter required to deliver one copy of the report to the person from whom the drug sample was taken and another copy to the person whose name and address was disclosed to him under Section 18A of the Act.

35. The Drugs Inspector is then required to retain the third copy to be used in prosecution in respect of such drug sample.

36. A drug whose quality is doubted is first required to be tested by the Government Analyst and the report of his test or analysis is to be supplied to the Inspector, and the Inspector is, in turn, required to inform the persons who will be directly affected by the test/analysis i.e., the

person from whom it is taken and/or the person from whom it was acquired (as disclosed under Section 18A), while retaining the third copy for being used in the prosecution that he may launch. This is the glaringly apparent purpose behind Section 25(1) and (2) of the Act and also Rule 45 and 46 of the Rules.

37. Obviously, the person who receives this report, if he accepts the results of the test, is expected to take immediate steps to ensure that said drug is not used.

38. Section 25(3) of the Act declares that the report of the Government Analyst would be evidence of the facts stated therein and it is also declared to be conclusive. However, it also gives a right to the person who has been furnished with the report, an opportunity to challenge it.

39. The law sets a time frame of 28 days to question the report, and it is required that the person challenging the report notifies this intention of adducing evidence in contravention of the report, in writing, to the Inspector. In

case of pending proceedings, the person can also state that he intends to adduce evidence before the Court in contravention of the report.

40. It is to be noticed here that it is only at this stage that the Inspector has definite material regarding the quality of the drug and the persons responsible for the drug (i.e., the person from whom it had been taken / acquired) and they are required to be put on notice about the drug with the adverse report of the Analyst. The fact that a specific time frame of 28 days is provided to react to the report indicates that the law mandates an immediate action by the concerned person regarding the drug. The further consequence of an inaction is also stated that if there is no challenge to the report within the time frame, the report becomes conclusive. This process indicates the urgency with which the matter is to be dealt with by all concerned i.e., the Inspector, the Analyst and the persons responsible for the drug.

41. If the use of the expression '*forthwith send to the Government Analyst'* in Section 23 (4)(i), the requirement of the Government Analyst to complete the testing/analysis of the sample drug and furnish the report to the Inspector forthwith in Rule 46 (and the period of sixty days prescribed under the amended Rule 45) coupled with the requirement of a time frame of 28 days to react to the report, when read in conjunction, makes it absolutely clear that the intention of the law is that the issue relating to the quality of the drug is to be resolved with utmost promptitude or at any rate within the prescribed period.

42. If, however, the Government Analyst were to take an inordinately long time to conduct the test/analysis of the drug, the very intent of the law would stand defeated. More importantly, the delay would enable the suspected drug to be in circulation, thereby exposing the public to serious consequences. This would also put the manufacturer in a piquant situation regarding the drug

that he has manufactured and which he has distributed for sale since he would not know what the fate of the drug is.

43. The fact that Rule 45 itself was amended on 02.02.2017, wherein the deadline of sixty days to conclude the test/analysis of a sample drug by a Government Analyst was inserted, clearly establishes that the requirement of conducting the test with promptitude is a must and there can be no delay in conducting the test/analysis.

44. It is therefore obvious that it is the clear legislative intent that the process of taking a sample of the drug, getting it tested by a notified Analyst and sending a copy of the report to the persons responsible for the Drug are to be undertaken with a sense of urgency so that the cloud of suspicion hanging on the drug is resolved promptly.

45. If the intention of the Legislature was to allow the Government Analysts to take their own sweet time to conduct the test/analysis and also enable the person

affected by the test to react to the report of the test leisurely, the fixation of time-frames under Sections 23 and 25 of the Act as well as Rule 45 of the Rules would be rendered redundant.

46. It is quite possible that the persons responsible for the drug can adduce evidence to the Inspector on the veracity of the report, and the Inspector may accept it and choose not to launch prosecution.

47. However, if he does decide to launch prosecution or if he has already launched prosecution, the manner of challenge to the report is indicated under Section 25(4) of the Act.

48. Section 25(4) of the Act deals with the situation following the reaction to the test report by the persons responsible for the drug and question it as provided in Section 25(3). It states that the Court may, in its discretion or at the request of either the complainant or the accused, cause the sample to be tested by the CDL

which has been established under Section 6 of the Act. However, this option is unavailable to the Court if the drug sample has already been tested by the CDL.

49. This sub-section (4) makes it obligatory for the CDL to conduct a test/analysis and send a report in writing (under the authority of the Director of the Laboratory, the highest post in the Laboratory) to the Court, and it further goes on to declare that the report of the test/analysis made by the CDL shall be conclusive evidence of the facts stated therein.

50. This would therefore indicate that the Court, before which proceedings have been launched, has the option of permitting the accused to adduce evidence, if he has reacted to the report within 28 days of receipt of the report *or* it has the discretion to send the sample to the CDL established under Section 6 of the Act and seek for a test to be conducted by CDL. On such a test being conducted and upon a report in this regard being sent to the Court, the report is declared to be conclusive and,

therefore, all the persons concerned, including the Court, becomes bound by the report.

51. It is for this reason that Section 23 (4)(ii) requires that the 2rd portion of the sample of the drug be produced by the Inspector before the Court, enabling the Court to send it directly to the CDL. This further mechanism of subjecting the sample of the drug to a *second and final test/analysis* by the statutory laboratory provided under the Act and making the report of this test conclusive is to basically ensure that there can be no doubt about the quality of the drug.

52. This mechanism is also to ensure that the Court is not burdened with the task of analyzing the evidence that the accused may adduce in contravention of the report of the Government Analyst. In the task of analyzing the evidence relating to a drug, which is obviously based on scientific parameters, the Court may not be equipped with the expertise to analyze the evidence, and the law therefore gives the Court the option to send it to the

premier laboratory established under the Act. This mechanism would also enable the accused to seek a second drug test in light of an adverse report of an earlier test conducted by the Government Analyst.

53. The ultimate effect of this provision is that the sample of the drug is tested for the second time when the 1st test is under challenge, and the results of the 2nd test, if in consonance and in conformity with the 1st test report, brings the curtains down on the quality of the drug and concludes the question regarding its quality.

54. It is to be noticed here that the accused has been conferred with the statutory right to request the Court to seek a reference to the CDL, despite availing the option of adducing evidence controverting the report of the Government Analyst. This report is a valuable right provided under the Statute and cannot, therefore, be ignored or diluted because the report of the CDL would be conclusive. If the CDL tests the sample and differs with the report of the Government Analyst, the entire proceedings

will have to come to an end as the report is declared to be conclusive evidence. Obviously, the Court cannot convict the accused in light of the report of the CDL and would have to necessarily acquit him.

55. The converse of this is also true that once a report is submitted by the CDL confirming the test report of the Government Analyst, the accused would not be able to question the report and would be bound by it, and he can establish his innocence on other grounds which may be available to him.

IV. APPLICATION OF THE LAW TO THE FACTS OF THIS CASE:

56. In the instant case, as far as the first sample is concerned, the Government Analyst received the sample on 04.03.2013 and he was required to conduct the test or analysis of the sample and submit the report to the Inspector which would have to be furnished to the petitioners and they had the right to challenge the report of the Government Analyst. This right to challenge the

report was effectively nullified by the delay in the conduct of the test of the sample by more than 20 months by which time the shelf life of the drug had also expired.

57. As already stated above, the date of expiry of the first sample was June, 2015 but the Government Analyst submitted a report nearly twenty-two months after he had received the report in May, 2015 and this was just before the expiry of the shelf-life of the subject drug.

58. The Drugs Inspector, in turn, secured the details of the manufacturer only after she received the report on 08.06.2015 and she then sent a copy of the report with the sample.

59. Since the report and sample were sent after the shelf-life of the drug sample had expired, the valuable right that the manufacturer had to dispute the veracity of the test report of the Government Analyst was taken away. The manufacturer also lost the right to adduce evidence in contravention of the report which was

furnished to him only in June, 2016, simply because he could not have the sample sent to him tested as its shelf life had expired in June, 2016 itself.

60. The manufacturer also had the right to request the Court to send the sample to the CDL for the 2nd and conclusive test and this right was also lost since, by the time the proceedings were initiated in September of 2016, the shelf life of the drug had expired and the Court could also not refer it to the CDL.

61. In my view, if this statutory right of the manufacturer to oppose the test report by either adducing evidence in contravention of the report *or* by requesting the Court to send the same for the 2nd and conclusive test to the CDL was taken away, the entire prosecution would be vitiated as the right of the accused to defend itself, as provided under the Act itself, had been taken away. It is thus obvious that the prosecution would only be a futile exercise.

62. In fact, in this case, it is to be noticed that the petitioner responded on 16.06.2015 and 23.06.2015, highlighting the fact that the test had been conducted 20 months after the drug samples had been secured from the ESI Hospital, and on their analysis, it was noticed that the test for drug release was within the accepted criteria.

63. Furthermore, they stated their intention to challenge the report and asked for the drug sample to be sent to the CDL. Obviously, since the shelf-life of the drug sample had expired by 23.06.2015, the chance of the petitioners to establish that the subject drug conformed to the test for drug release and could not thus be termed as '**not of standard quality**' was completely defeated.

64. This inordinate delay of the Government Analyst in testing the sample and submitting a report has resulted in serious prejudice to the petitioners. Since the right of the petitioners to challenge the report has been snatched away, the entire proceedings could be vitiated.

65. It is also to be noticed here that if the test report had been obtained within a short span of time from the subject drug being sent to the Government Analyst and petitioner No.1 (being the manufacturer of the subject drug), on being given the copy of the report, had challenged the report, then, in the event the Drugs Inspector prosecuted the petitioners immediately, the manufacturer had the right to seek a reference and request the Magistrate to refer the matter to the CDL or adduce evidence before the Magistrate, refuting the report.

66. The Magistrate could have either accepted the evidence or resorted to referring the drug sample to the CDL, whose report was conclusive. Since this valuable right has been taken away, the proceedings challenged in the present petition would stand vitiated.

67. As far as the second sample is concerned **(Batch No.F957 C404)**, this sample was taken on 12.06.2014 and it was sent immediately to the Government Analyst, who conducted the test nearly five months thereafter,

between 10.11.2014 and 12.11.2014. Eight months after conducting the test, the Government Analyst submitted a report on 15.07.2015 to the effect that the subject drug did not pass the drug release test.

68. It may be pertinent to notice here that even in this case, the Government Analyst has taken thirteen months (from 12.06.2014 to 15.07.2015) to send his report and the Drugs Inspector has thereafter initiated action i.e., sending the report and the sample to petitioner No.1–Company to obtain their response.

69. Another important factor to be noticed here that in respect of the first batch of the sample drugs **(Batch No.F957 G220)**, on the receipt of the report, a joint investigation was conducted by the Drugs Inspector, CDSCO, West Zone, Mumbai and the Drugs Inspector, FDA, Nagpur on 13.08.2015. Pursuant to this joint investigation, a report dated 28.08.2015 was sent with an opinion that the controlled sample available with petitioner No.1 complied with the test for drug release and the

received portion of the sample also passed the test at L2 stage.

70. This investigation report was shared with the Drugs Inspector, Bangalore. This would also indicate that the test/analysis conducted by the Government Analyst was not reliable. In the background of this particular fact, it is obvious that the prosecution in respect of the 2nd sample was also vitiated. Furthermore, the right of the accused–manufacturer to request the Court to refer the drug sample to the CDL has also been rendered impossible by efflux of time, considering the obvious fact that the shelf life of the drug has expired.

71. Though the prosecution is liable to be quashed on the above-mentioned reasons, there is one other issue which was argued at length and is therefore required to be dealt with.

72. The learned counsel for the petitioners also put forth the argument that the launch of prosecution against the

Company, its Chairman, Managing Director and Executive Director was illegal, inasmuch as the complaint did not indicate the manner in which the Chairman, Managing Director and Executive Director were responsible for the conduct of business. He submitted that it is settled law that the complaint should specifically aver that the persons accused and named in the complaint were directly responsible and also indicate the manner in which they were responsible. In this regard, he places reliance on the decision rendered by the Hon'ble Supreme Court in the case of ***Lalankumar Singh***[3].

73. The counsel for the petitioner has also relied on the following judgments to contend as below:

i. **Alembic Pharmaceuticals Ltd. & Ors. v. State of Karnataka & Anr., *Crl.P. 100700/2018 – 28.09.2018 – HCK (Dharwad)***: non-application of mind by the Magistrate while taking cognizance would vitiate the subject proceedings;

[3] Lalankumar Singh & Ors. v. State of Maharashtra, *2022 SCC OnLine SC 1383*.

ii. **M/s. Cosmas Pharmacals Ltd. & Ors. v. State of Karnataka,** ***Crl.P. 100661/2023 – 19.12.2023 – HCK (Dharwad)*****; M/s. Stadmed Pvt. Ltd. & Ors. v. Union of India,** ***Crl.P. 891/2017 – 11.12.2022 – HCK (Bangalore)*****; M/s. Perennial Medicare & Anr. v. State at the Instance of Drugs Inspector,** ***Crl.P. 2830/2017 – 24.05.2022 – HCK (Bangalore)*****; Sri. Himanshu Baid & Ors. v. State of Kerala,** ***Crl.M.C. No.329/2010 – 17.03.2010 – Kerala HC*****;** and **Serdia Pharmaceuticals (India) Pvt. Ltd. v. Union of India,** ***Crl.P. 919/2020 – 24.03.2021 – HCK (Bangalore):*** that by virtue of the subject drug having expired, the petitioner—Company lost its right to further test and challenge the Government Analyst's report;

iii. **Ritesh & Ors. v. the State of Karnataka & Ors.**, ***Crl.P. 15263/2011 and connected matters – 19.11.2011 – HCK (Gulbarga)*****;** and **Sri. Sushil Goel & Ors. v. State at the Instance of Drugs Inspector,** ***Crl.P. 6875/2020 – 10.05.2022 – HCK (Bangalore)***: the specific role of the petitioners herein — that by virtue of their positions as the Director/members of the higher management of the Company, they were directly involved in the day-to-day affairs of the Company which resulted in

the subject drug to be "*not of standard quantity*" — has not been mentioned in the complaint, and the same would thus have to be quashed;

iv. **Ramprakash Gulati & Ors. v. State of Maharashtra, *Crl. Application No.3684/2009 – 01.09.2017 – Bombay HC (Nagpur);*** and **Siby Thomas v. M/s. Somany Ceramics Ltd., *SLP (Crl.) No. 12/2020 – 10.10.2023 – the Hon'ble Supreme Court***: direct averments, which are to be mandatorily specified against the petitioners herein, are absent — *this case, however, deals with a complaint filed under Section 138 r/w Section 141 of the Negotiable Instruments Act, 1881*.

74. Mr. Deshpande, *per contra*, contended that this argument was without any substance. He submitted that the Drugs Inspector had conducted the investigation strictly in accordance with the statutory Rules and during the course of the statutory investigation, he had secured information of the persons responsible for the conduct of business of the Company and the correspondences were also produced along with the complaint, and, therefore, even if specific averments were not made in the

complaint, as the entire investigation papers were submitted to the Magistrate, the requirement of the law had been complied with.

75. He also relied on the following citations in support of his contentions:

i. **Union of India v. Ashok Kumar & Ors.,** ***(2021) 12 SCC 674*****;** and **Jeewan Kumar Raut & Anr. v. Central Bureau of Investigation,** ***(2009) 7 SCC 526***: the Officer was duly notified as an "Inspector" under the Act, empowering him to collect the subject drug and cause the same to be tested by a Government Analyst. Further, such Inspector was also duty-bound and authorised to file a complaint before the Sessions Court to take cognizance of the same. Hence, no defects could be raised on jurisdiction;

ii. **State of Gujarat v. Afroz Mohammed Hasanfatta,** ***(2019) 20 SCC 539***: when taking cognizance for an offence under the Act, the Magistrate need not specify reasons for issuing summons based on *prima facie* evidence. The only requirement is that he/she is satisfied that there are sufficient grounds to issue the same;

iii. **Serdia Pharmaceuticals (India) Pvt. Ltd. v. Union of India (*supra*) – *HCK (Bangalore)*** *affirmed by the Hon'ble Supreme Court in* **Serdia Pharmaceuticals (India) Pvt. Ltd. v. Union of India**, ***SLP (Crl.) No. 5053/2021 – 13.02.2024***;

iv. **Dinesh B. Patel & Ors. v. State of Gujarat & Anr., *(2010) 11 SCC 125;*** and **Vikas Rambal & Ors. v. the State represented by the Drugs Inspector, *Crl.O.P. No.11184 of 2019 & Crl.M.P. No.5726 of 2019 – 12.10.2022 – Madras HC***: Directors could be held liable for the affairs of the Company if the drug manufactured by their Company for human consumption was found to be defective;

v. **Glaxosmithkline Pharmaceuticals Ltd. & Anr. v. State of Madhya Pradesh, *(2011) 13 SCC 72***: option given under the Act to challenge the Government Analyst's report within 28 days and such report becomes conclusive *if the expiry date of the drug has passed in the meantime*.

76. The Hon'ble Supreme Court in the case of ***Lalankumar Singh*** (*supra*) has reiterated the case of ***Brij Lal Mittal***[4] wherein it is categorically held as follows:

[4] State of Haryana v. Brij Lal Mittal, *(1998) 5 SCC 343.*

> *"8. Nonetheless, we find that the impugned judgment of the High Court has got to be upheld for an altogether different reason. Admittedly, the three respondents were being prosecuted as directors of the manufacturers with the aid of Section 34(1) of the Act which reads as under:*
>
> > *"34. Offences by companies.— **** commission of such offence."*
>
> *It is thus seen that the vicarious liability of a person for being prosecuted for an offence committed under the Act by a company arises if at the material time he was in charge of and was also responsible to the company for the conduct of its business. Simply because a person is a director of the company it does not necessarily mean that he fulfils both the above requirements so as to make him liable. Conversely, without being a director a person can be in charge of and responsible to the company for the conduct of its business. From the complaint in question we, however, find that except a bald statement that the respondents were directors of the manufacturers, there is no other allegation to indicate, even prima facie, that they were in charge of the company and also responsible to the company for the conduct of its business*."

77. In view of this clear declaration of law, it is obvious that the complaint should categorically state the manner in

which the persons accused in the complaint were responsible for the conduct of the business and in the manufacturing of the subject drug. However, in the instant case, as already extracted above, the complaint merely alleged that all the accused were responsible for the manufacture of the subject drug. Since the dictum of the Hon'ble Supreme Court has not been complied with, the complaint cannot be sustained.

78. An argument was also sought to be advanced by Mr. Deshpande that the Drugs Inspector was conducting a statutory investigation and the entire papers relating to the investigation were placed before the Magistrate, and, therefore, a hyper-technical view that the complaint should also state the manner in which the accused were responsible was not necessary.

79. He submitted that an investigation conducted in accordance with the statutory provisions cannot be equated with a complaint presented by any other person under Section 200 of the CrPC, and certain credence must

be given to such statutory investigation conducted by the Drugs Inspector, who also trace their power to a statute.

80. In my view, this argument of Mr. Deshpande cannot be accepted. Chapter XV of the CrPC relates to complaints that can be given to the Magistrate.

81. "**Complaint**" has been defined under Section 2(d) of the CrPC to mean "*any allegation made orally or in writing to a Magistrate with a view to his taking action under the Criminal Procedure Code, that some person, whether known or unknown, has committed an offence, but does not include a police report*". This definition clearly excludes a police report, but the explanation appended to this definition states that a report made by a police officer after investigation, which indicates the commission of a non-cognizable offence, is deemed to be a complaint, and, in such an event, the police officer who makes the report is deemed to be the complainant.

82. Thus, if a person makes an allegation in oral or in writing to a Magistrate, it becomes a complaint, and it doesn't matter whether that person is a private citizen or a public servant. This Section makes it clear that it is only if a police officer has conducted the investigation regarding the commission of a non-cognizable offence and has submitted a report, it is deemed that his report is a 'complaint'.

83. In light of the fact that the explanation clearly refers only to a police officer who investigates the commission of a non-cognizable offence and the report made by that police officer can only be deemed to be a complaint, the argument that the complaint presented by the Drugs Inspector should be treated on par with the report of a police officer cannot be accepted.

84. Since the explanation to Section 200 has not included an investigation made by a public servant under any enactment to be a deemed complaint, it cannot obviously confer the status of a police officer on a public

servant conducting investigation for an offence under any other enactment.

85. Section 200 of the CrPC enables a complaint to be given to a Magistrate, and the Magistrate is thereafter empowered to take cognizance of the offence, and this in law, is the initiation of criminal proceedings.

86. Section 200 thereafter casts an obligation on the Magistrate who has taken cognizance to examine upon oath the complainant and the witnesses present. It requires that the substance of such an examination should be reduced in writing and signed by the complainant, the witnesses and also by the Magistrate.

87. However, when a complaint is made in writing, the proviso to Section 200 of the CrPC makes an exception and dispenses with the obligation of the Magistrate to examine the complainant and the witnesses, if a public servant acting or purporting to act in the discharge of his official duties has made the complaint.

88. Thus, as against normal procedure of examining the complainant on oath, when a complaint is presented to a Magistrate by a public servant, the Magistrate is not required to examine him on oath and is also not required to reduce the substance of such a complaint in writing. This is obviously because a public servant is presumed to act responsibly when he makes a complaint, and there would be no need to have any kind of safeguard to make a public servant liable if the statements are found to be incorrect since this action can be taken without any difficulty, as compared to taking action against a private citizen.

89. As stated above, the explanation under Section 2(3) of the CrPC is confined only to a police officer and not to a public servant. A public servant, therefore, would have to necessarily present a set of allegations orally or in writing to the Magistrate, and it is this set of allegations which is to be looked into by the Magistrate for taking cognizance and the proceedings would thereafter stand initiated.

90. It is therefore clear that a complaint presented by a public servant such as the Inspector, if against a Company, its Chairman, Managing Director and Director, is required to conform to the law of making specific allegations against each of the accused as declared by the Apex Court in the case of ***Brij Lal Mittal Mittal*** and reaffirmed in ***Lalankumar Singh*** referred to above.

91. Even considering the judgment of the Apex Court relied upon by Mr. Deshpande for the respondents rendered in the case of ***Dinesh B. Patel*** (*supra*), which has considered and distinguished ***Brij Lal Mittal*** (*supra*), there were specific averments in said case that the Directors therein were privy to the manufacturing of the subject drug therein and it was thus necessary that they be made liable. In the instant case, however, no averments to that effect have been made. While ***Dinesh B. Patel*** makes Directors liable for the manufacturing of a drug, it also meted out the indispensable requirement that specific averments were necessary in the complaint to

demonstrate that the Director/higher management officials of such company *were privy to* OR *were directly involved* in the manufacturing of the subject drug.

92. Even if the Inspector has been notified and has jurisdiction to present a complaint before the Sessions Court as per ***Ashok Kumar*** and ***Jeewan Kumar Raut*** (both cited *supra*), the fact remains that the drug had expired before it was even tested by the Government Analyst, thus not rendering the petitioners herein a fair opportunity to challenge the Government Analyst's report. Reliance placed on ***Afroz Mohammed Hasanfatta*** and ***Glaxosmithkline*** (both cited *supra*) to urge that the Magistrate need not specify reasons for issuing summons based on prima facie evidence and that 28 days were provided to the petitioners herein to challenge the report which became conclusive upon the expiry of the drug in the meantime, is a misconceived argument, and these judgments do not aid the grounds raised by Mr. Deshpande for *two reasons*: 1. that the Magistrate, by

taking cognizance of a report based on the testing of an expired drug, has displayed clear non-application of mind; and 2. since the drug itself expired before the test was conducted by the Government Analyst, there is no question of subjecting it to further testing in order to challenge the Analyst's report.

93. Now coming to the facts of the present case, as narrated above, the allegations as far as the officers / accused are concerned was as follows:

> *"47. The complainant submits the accused 2 is the Chairman, 3 is the managing director & 4 is the executive director of the company that is accused no.1 and A5 to A8 who are the manufacturing and analytical chemist are responsible for manufacturing & analyzing / testing the substandard drug with a mala fide intention in order to have unlawful gain and they are liable for criminal prosecution, hence the above complaint."*

94. As could be seen from the above, the complaint merely states that the Chairman–Accused No.2, the Managing Director–Accused No.3 and the Executive Director–Accused No.4 of the Company along with three others (Accused Nos.5 to 7) i.e., the Manufacturing and the Analytical Chemists were responsible for manufacturing, analyzing and testing the sub-standard drug.

95. The Apex Court as already noticed above in its judgment rendered in ***Brij Lal Mittal*** and reiterated in ***Lalankumar Singh*** (*both supra*) which was also arising out of a complaint in writing under the Act, after taking note of every judgment rendered in relation to offences under the Act, has held that the complaint is required to specifically aver wrongdoings on each of the accused and a general allegation would not suffice.

96. It is thus clear that the complaint against accused Nos.2 to 4, i.e., the Chairman, Managing Director, and Executive Director should have categorically stated as to

how and in what manner they were responsible for the conduct of the business of the Company. Admittedly, even according to the complaint, these three persons were not responsible for the manufacturing of the drug and from the post that they were holding, and it cannot be presumed that they were, by themselves, responsible for the conduct of the business of the Company in terms of production of the subject drug. It is thus clear that the complaint lodged against accused Nos.2 to 4 is unsustainable.

97. As far as the other accused are concerned (Accused Nos.5 to 7), as already noticed above in relation to the first sample, the Government Analyst, by not conducting the test/analysis from 11.03.2013 to till 10.11.2014, has ensured that the right of the manufacturer to challenge the test/analysis report has been defeated.

98. The further fact that he has taken six more months from 10.11.2014 till 05.05.2015 to send the report after being aware of the fact that the drug sample would expire

in June, 2015, has ensured that the right of the manufacturer to challenge the test/analysis report is completely defeated.

99. The Inspector has contributed to this inordinate delay by calling upon the ESI Hospital to furnish the name and address of the manufacturer under Section 18A of the Act only after she received the report. By the time this information was received on 08.06.2015, the shelf-life of the drug had expired and, therefore, the right that the manufacturer possessed to challenge the veracity of the test/analysis report was also defeated.

100. It may also be pertinent to notice here that at the request of the manufacturer, a joint analysis of this sample was conducted before concluding that the controlled sample complied with the test for drug release and that the received portion passed the test at L2 stage.

101. This, by itself, proves that there were contradictory reports — one report stated that the sample drug did not

pass the test relating to the release of the drug; while the other report stated that it had passed the test.

102. It is hence clear that there could be no justification to continue the prosecution when the joint investigation by the Drug Inspector, CDSCO, West Zone, Mumbai and the Drug Inspector, FDA, Nagpur Zone had concluded that the sample drug did pass the drug release test.

103. As far as the second sample is concerned, the other Government Analyst received the sample in June, 2014 but again, he took five months to conduct the test and took a further period of seven months to send his report. The Government Analyst thus took more than a year to conduct the test/analysis and submit his report. This report was also to the effect that the drug did not pass the test for drug release. Even in this case, the Drugs Inspector called upon the ESI Hospital to furnish the details of the manufacturer only after she received the report from the Government Analyst and, thereafter,

notified petitioner No1.–Company, who immediately responded challenging the test report.

104. Even in the case of second sample, the complaint cannot succeed because of the fact that the averments in paragraph 47 are vague, insofar as involvement of accused Nos.2 to 4 is concerned.

105. Having regard to the fact that the very same drug sample was subjected to a joint investigation in August, 2015 (of the first sample) and it was held that it did pass the test for drug release, the test conducted on the second drug sample also cannot be accepted.

V. CONCLUSION:

106. The impugned proceedings as against the petitioners are therefore, in their entirety, ***quashed***.

107. The criminal petitions are ***allowed*** accordingly.

108. In view of the disposal of the petition, all pending interlocutory applications, if any, stand disposed of.

VI. DIRECTIONS:

109. Before parting with the case, it is necessary to make certain observations and issue certain directions regarding the manner in which the entire process was conducted and by the Drugs Inspector as well as the Government Analysts.

110. As already noticed above, the investigation process prescribed under the Act contemplates taking of the drug sample. The first step is to secure the drug, divide it into four portions, handover one portion to the person from whom the drug sample was obtained, and immediately send the second portion to the Government Analyst for test/analysis. The third portion is required to be retained by the Drugs Inspector if proceedings are to be initiated on the basis of said drug sample.

111. Since the statutory procedure requires that one portion needs to be sent for test/analysis, it would be incumbent upon the Inspector to simultaneously call for and secure the information regarding the particulars of

manufacturer of the drug sample, as provided under Section 18A of the Act. This is necessary because the moment (s)he receives the test/analysis report from the Government Analyst under Section 22 of the Act, (s)he is required to send one copy to the person from whom the drug sample was obtained and, more importantly, send the second copy to the person from whom the drug was procured i.e., the manufacturer whose details were being furnished under Section 18A of the Act.

112. The fact that the report of the Government Analyst is required to be sent to the person whose details were furnished under Section 18A of the Act presupposes that the Drugs Inspector has to have this information in his/her possession by the time he receives the report from the Government Analyst.

113. The procedure adopted in this case of securing the information of the manufacturer after receipt of the report from the Government Analyst basically defeats the entire statutory mandate.

114. For this reason, henceforth, the Inspectors under the Act are directed to ensure that they secure information relating to: (a) the person from whom the drug was acquired (as provided under Section 18A of the Act); and (b) the place where the drug was manufactured (as provided under Section 24 of the Act) — at the same time that they send the drug sample for test/analysis to the Government Analyst. Thereafter, on receipt of the report, (s)he is further directed to immediately forwards the same to the manufacturer of the drug and whose details are provided under Section 18A of the Act.

115. In this case, it is also to be noticed here that the Government Analyst is required to test the drug to ensure that there are no ill-effects by the use of such drugs to the general public. By an insertion to Rule 45 of the Rules in 2017, a time limit of 60 days is prescribed for the conduct of the test and for sending of the report by the Analyst.

116. If a Government Analyst takes several months or, as in this case, more than a year to conduct the test/analysis

and submit their report, the possibility of the drug continuing in circulation, thereby exposing the public to its ill-effects is clear and present.

117. The Inspector also cannot initiate action against the manufacturer until he has secured the report from the Government Analyst and has furnished a copy of such report to the manufacturer.

118. The Drugs Controller General (India), CDSCO, New Delhi is therefore directed to issue proper directions to the Government Analysts to ensure that the test/analysis of the drug sample sent to them is conducted without any delay and within the period of sixty days prescribed in Rule 45 from 2017.

119. The Drugs Controller General (India) is also directed to ensure that an efficient online system is created, whereby the drug samples which are sent for test/analysis are expeditiously tested and analyzed by the Government Analyst within sixty days, and the reports sent by them

are available online on a real-time basis. This creation of an effective mechanism to ensure that the entire process is monitored, and unnecessary delay is not caused in the conduct of the test/analysis of the drugs sample sent for test to the Government Analysts would ensure that the ill-effects of a drug of doubtful quality is prevented.

120. The Drugs Controller (General) shall preferably ensure that this entire process be web-hosted so that that all the concerned are aware of the process of testing and its outcome.

121. A report of compliance of these directions is be furnished to this Court within a period of ***eight*** weeks from today.

122. The Registry is directed to send a copy of this order to the Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), FDA Bhavan, Kotla Road, New Delhi-110 002, forthwith.

123. Re-list the matter on ***28.10.2024*** for reporting compliance.

Sd/-
(N S SANJAY GOWDA)
JUDGE

RK
CT: SN
VC List; Sl No.:11