IN THE HIGH COURT OF JUDICATURE AT BOMBAY
BENCH AT AURANGABAD

CRIMINAL WRIT PETITION NO. 28 OF 2003

1. Anandkumar s/o Satyanarayan Loya,
Age 53 years, Occ Business,
R/o. Chintamani Colony,
Urogenital

2. Shankarlal s/o Ratanlal Jhawar,
Age 53 years, Occ. Business
R/o. M/s. Amrit Pharmaceuticals,
G-5, Industrial Area,
Chikalthana, Aurangabad ...Petitioners

versus

1. The State of Maharashtra
(Through the Public Prosecutor
High Court, Bench at Aurangabad)

2. Drug Inspector,
Food and Drugs Administration,
(M.S.), Aurangabad ...Respondents

WITH
CRIMINAL WRIT PETITION NO. 29 OF 2003

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2. Drug Inspector,

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(M.S.), Aurangabad ...Respondents

WITH
CRIMINAL WRIT PETITION NO. 30 OF 2003

1. Anandkumar s/o Satyanarayan Loya,
Age 53 years, Occ Business,
R/o. Chintamani Colony,
Urogenital

2. Shankarlal s/o Ratanlal Jhawar,
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(Through the Public Prosecutor
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2. Drug Inspector,
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(M.S.), Aurangabad ...Respondents

WITH
CRIMINAL WRIT PETITION NO. 31 OF 2003

1. Anandkumar s/o Satyanarayan Loya,
Age 53 years, Occ Business,
R/o. Chintamani Colony,
Urogenital

2. Shankarlal s/o Ratanlal Jhawar,
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versus

1. The State of Maharashtra
(Through the Public Prosecutor
High Court, Bench at Aurangabad)

2. Drug Inspector,

Food and Drugs Administration,
(M.S.), Aurangabad ...Respondents

WITH
CRIMINAL WRIT PETITION NO. 32 OF 2003

1. Anandkumar s/o Satyanarayan Loya,
Age 53 years, Occ Business,
R/o. Chintamani Colony,
Urogenital

2. Shankarlal s/o Ratanlal Jhawar,
Age 53 years, Occ. Business
R/o. M/s. Amrit Pharmaceuticals,
G-5, Industrial Area,
Chikalthana, Aurangabad ...Petitioners

versus

1. The State of Maharashtra
(Through the Public Prosecutor
High Court, Bench at Aurangabad)

2. Drug Inspector,
Food and Drugs Administration,
(M.S.), Aurangabad ...Respondents

WITH
CRIMINAL WRIT PETITION NO. 33 OF 2003

1. Anandkumar s/o Satyanarayan Loya,
Age 53 years, Occ Business,
R/o. Chintamani Colony,
Urogenital

2. Shankarlal s/o Ratanlal Jhawar,
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2. Drug Inspector,

Food and Drugs Administration,
(M.S.), Aurangabad ...Respondents

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Mr. S.G. Ladda h/f Mr. Joydeep Chatterji, advocate for the petitioners
Mr. P.G. Borade, A.P.P. for respondents

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CORAM : V. K. JADHAV, J.

Date of Reserving the Judgment : 06.10.2016

Date of pronouncing the Judgment : 27.10.2016

JUDGMENT:-

1. The petitioners assail the common judgment and order dated 17.10.2002 passed by the learned Additional Sessions Judge, Aurangabad in Criminal Revision Nos. 203 of 2001, 204 of 2001, 205 of 2001, 206 of 2001, 207 of 2001 and 211 of 2001 (Anandkumar and another vs. State of Maharashtra and another), thereby dismissing the said revisions and confirming the common order passed by learned Chief Judicial Magistrate, Aurangabad, rejecting thereby the petitioners' application for discharge/dropping of proceedings.

2. Brief facts, giving rise to the present criminal writ petitions are as follows:-

a) The respondent Drug Inspector had filed six separate complaints in the court of Chief Judicial Magistrate, Aurangabad against the present petitioners for having committed offence under Sections 18 (1) (a) of the Drugs and Cosmetics Act 1940 (hereinafter referred to as the “Act of 1940”) punishable under Sections 27 and 34 of the Act of 1940. In all the cases, the petitioners are the same. The petitioners accused appeared in those cases and filed their applications at Exh.43, 39, 42, 43, 23 and 39 respectively, praying therein to drop the proceedings or close the cases.

b) The respondent Drug Inspector on various dates, drew the samples of sodium chloride injection from General Hospital Bhandara, Sangli and Grant Medical College, J.J. Mumbai. After obtaining the samples, the respondent Drug Inspector had sent the said samples of sodium chloride injection referred to in the proceedings to the Government Analyst, Maharashtra. According to the respondent Drug Inspector, he received the report from the Government analyst in respect of the said samples to the effect that it was not of standard quality, as defined under the provisions of Act of 1940 and the Rules framed thereunder, because the samples contained suspended matter visible to the unaided eyes. Thus, the respondent Drug Inspector had delivered a copy of the said report to

the Pharmacists of the Hospital as referred above and informed the Hospital authorities, not to use the said stock and return the same to the manufacturer. The said samples were drawn from the lot 3907 L-1. The hospital authorities intimated the Drug Inspector that said bottles were directly purchased from Amrit Pharmaceuticals, Aurangabad. It is alleged that thereafter another Drug Inspector delivered the copies of the report of the Government analyst to the petitioner Shankarlal. The respondent Drug Inspector had thereafter filed six separate complaints in the Court on 21.6.1988 against the petitioners.

3. Learned counsel for the petitioners submits that in terms of provisions of sub-section (3) of section 25 of the Act of 1940, both the petitioners had notified to the Drug Inspector in writing within a period of 28 days under certificate of posting that the report of the Government analyst was absolutely incorrect and unreliable. The petitioners intended to adduce evidence in contravention to the said report at the appropriate time. Furthermore, the petitioners on the date on which they appeared before the court, in response to the summons, filed applications in all the complaints in terms of provisions of sub-section (4) of Section 25 of the Act of 1940 pointing out to the Court that samples are not produced before the court alongwith the complaints and that the petitioners want to adduce

evidence contrary to the report of the Government analyst. The petitioners in the said applications requested the Court that the application be kept on record and their right to adduce evidence contrary to the report of the Government analyst be reserved and that the petitioners would make necessary application under Section 25(4) of the Act of 1940 at appropriate stage. Learned counsel submits that the respondent Drug Inspector has failed to produce the samples in the Court in time and produced it after expiry of the shelf life of the said Drugs. Thus, the same will amount to denial of valuable right to the petitioners to get the samples tested from the Central Laboratory. Learned counsel submits that, as per the chart which is reproduced herein below, due to delay in launching the prosecution and further by not producing the samples before the court though mandatory under the provisions of Sub section (4) of Section 23 of the Act of 1940, the report of the Government Analyst cannot be said to be conclusive and since the petitioners have lost their valuable right, serious prejudice has been caused to their defence. The continuation of the prosecution against the petitioners would be abuse of Court process.

CRI. W.P. NO.	NAME OF DRUG	SAMPLE DRAWN FROM	DATE OF ANALYSIS REPORT	DATE OF INTIMATION TO DRUG INSPECTOR U/S. 25(3)	DATE OF SUMMONS TO APPEAR	DATE OF APPLICATION U/S 25(4) DTO COURT
CRI. WP. NO. 28/2003	SODIUM CHLORIDE INJECTION , MFG DT. APRIL 1987, EXPIRY DT. SEPT. 1988	GENERAL HOSPITAL, BHANDARA	REPORT IS DT. 27/10/1987 "The sample contains suspended matter visible to unaided Eye" (Copy delivered on 24/03/1988)	04/04/1988 through Post	16/12/1988	16/12/1988
CRI. WP. NO. 29/2003	SODIUM CHLORIDE AND DEXTROSE INJECTION , MFG DT. JAN. 1987, EXPIRY DT. JUNE 1988	GENERAL HOSPITAL, SANGLI	REPORT IS DT. 13/07/1987 "The sample contains suspended matter visible to unaided Eye" (Copy delivered on 23/12/1987)	24/12/1987 through Post	16/12/1988	16/12/1988
CRI. WP. NO. 30/2003	SODIUM CHLORIDE INJECTION , MFG DT. JUNE 1987, EXPIRY DT. NOV. 1988	GRANT MEDICAL COLLEGE, J.J. MUMBAI	REPORT IS DT. 15/09/1987 "The sample contains suspended matter visible to unaided Eye" (Copy delivered to 19/01/1988)	03/02/1988 through Post	21/11/1992	21/11/1992
CRI. WP. NO. 31/2003	COMPOUND SODIUM LACTATE, MFG DT. JAN. 1987, EXPIRY DT. JUNE 1988	GENERAL HOSPITAL, SANGLI	REPORT IS DT. 18/03/1987 "The sample contains suspended matter visible to unaided Eye" (Copy delivered to	22/12/1987 through Post	16/12/1988	16/12/1988

			21/12/1987)			
CRI. WP. NO. 32/2003	SODIUM CHLORIDE INJECTION , MFG DT. FEB. 1987, EXPIRY DT. JULY 1988	GENERAL HOSPITAL, SANGLI	REPORT IS DT. 17/03/1987 "The sample contains suspended matter visible to unaided Eye" (Copy delivered to account on 23/12/1987)	24/12/1987 through Post	16/12/1988	16/12/1988
CRI. WP. NO. 33/2003	SODIUM CHLORIDE INJECTION , MFG DT. MAY 1987, EXPIRY DT. SEPT. 1988	GENERAL HOSPITAL, BHANDARA	REPORT IS DT. 27/10/1987 "The sample contains suspended matter visible to unaided Eye" (Copy delivered to 24/03/1988)	04/04/1988 through Post	16/12/1988	16/12/1988

Learned counsel for the petitioners submits that as per the standard mentioned in the Indian Pharmacopoeia, pertaining to sodium chloride intravenous infusion, the requirements of storage is in a single dose containers of glass or plastic, in a cool place. The substances and preparations of the pharmacopoeia are to be stored under conditions that prevent contamination and, as far as possible, deterioration. Specific directions have been given with respect to temperature at which sodium chloride injection should be stored. In a "cool" place means any temperature between 8° and 25°. It is further mentioned in respect of sodium chloride injection that on

keeping, small solid particles may separate from glass container. It has further directed that label shall state (i) The strength as the percentage w/v of sodium chloride; and (ii) that a solution containing visible particles must not be used. So far as the samples drawn by the respondent Drug Inspector in the present matters are concerned, it has specifically mentioned on the label that the solution containing visible particles must not be used. Learned counsel submits that the development of visible solid particles is a natural phenomena during storage, if there is variation in temperature, for which the manufacturer cannot be held responsible. The Government analyst report does not indicate that there are foreign materials in the Drugs. Learned counsel submits that the said Drug cannot be said to be of substandard quality, due to visibility of the suspended matters, as the said particles are likely to develop, if the drug is not stored in a cool place. It is a part of record that the said samples were not collected from the manufacturer and after considerable gap from the date of manufacture, the said samples were drawn from the stores of respective hospitals.

Learned counsel for the petitioners submits that the report of the Government analyst does not state the protocols of the test applied. In absence of that, the petitioners accused may not get the full information of the test applied and consequently, it is not possible

for them to controvert the result by adducing the evidence. The complaints in all the cases are filed just before expiry of the shelf life of the product. It deprives the petitioners to exercise their valuable right, as provided under the provisions of Section 25(3) and 25(4) of the Act of 1940.

Learned counsel for the petitioners submits that there are no averments in the complaints that the present petitioners are in charge and responsible to the conduct of business of the firm. It has simply alleged in the complaints that on the basis of power of attorney, the petitioners herein are looking after the day-to-day affairs of the firm. It is nowhere alleged in the complaints, that the petitioners herein are looking after the production side and they are responsible for the business of the company with regard to the same. Learned counsel submits that there is no compliance of Section 34 of the Act of 1940.

Learned counsel for the petitioners, in order to substantiate his submissions, placed reliance on the judgments in the following matters:-

i) Narendrakumar vs. State of Maharashtra, reported in 2002 Bom.C.R. (Cri.) 93

ii) Shyam Madanmohan Ruia and others vs. M.R. Mahakalkar and

another reported in 1997 BCI 103

iii) Drugs Inspector, Central Drugs Standard Control Organisation (South) Zone, Madras-6 vs. M/s. Modern Drugs and another reported in 1982 Cri. L.J. 2285

iv) M/s. Prem Pharmaceuticals and others vs. State of M.P. Reported in 1989 Cri. L.J. 2028

v) Municipal Corporation of Delhi vs. Ghisa Ram reported in AIR 1967 S.C. 970

vi) State of Maharashtra vs. Vasudeo Shivlingappa Takawade and another reported in 1988(3) Bom. C.R. 207

vii) Plethico Pharmaceuticals and others vs. State of Maharashtra reported in 2002 Bom. C.R. (Cri.) 402

viii) Umesh Sharma and another vs. S.G. Bhakta and others reported in 2003 Bom. C.R. (Cri.) 1522

ix) Venkaiah Chowdary Nannapaneni and others vs. State of Maharashtra reported in 2003 All MR (Cri) 758

x) Municipal Corporation of Delhi vs. Ram Kishan Rohtagi reported in 1982 DGLS(SC) 203

xi) Raj Kishan vs. State reported in 1976 Drugs Cases 52

xii) M/s. Medicamen Biotech Limited and another vs. High Court of Delhi, Vineeta Goyal vs. Rubina Bose, Drug Inspector reported in AIR 2008 SC 1939

4. Learned A.P.P. for the respondent submits that the respondent Drug Inspector has followed all procedure while drawing the samples. The petitioners never approached the respondent Drug Inspector in terms with the provision of sub section (3) of Section 25 of the Act of 1940, notifying in writing thereby that they intend to adduce evidence in contravention of the report of Government analyst. Even the petitioners have not annexed the copy of the said application purportedly filed under Section 25(3) of the Act of 1940 alongwith the writ petitions. Even the petitioners accused have not filed any application before the learned Magistrate in terms of the provisions of sub-section (4) of Section 25 of the Act of 1940. The petitioners have only reserved their right to file application under the said provisions. In absence of any application before the court under the provisions of sub-section (4) of Section 25 of the Act of 1940, no prejudice is caused to the defence of the accused, nor the petitioners have been deprived to exercise their valuable right in terms of provisions of sub-section (4) of Section 25 of the Act of 1940. The Government analyst report is self-explanatory and by unaided eyes, suspended material in the sample were visible. Further, in terms of power of attorney issued in favour of the petitioners by other partners, the petitioners are looking after the business of the firm and

respondent Drug Inspector has made the averments in the complaints to that effect. In terms of the standard prescribed by the Indian Pharmacopoeia, it is clear that the said sample was substandard. Prima facie case is made out against the petitioners and, therefore, learned Chief Judicial magistrate has rightly rejected their application for dropping out the proceeding and further, the learned Additional Sessions Judge in revision confirmed the said order passed by the learned Chief Judicial Magistrate. No interference is required and all writ petitions are liable to be dismissed.

Learned A.P.P. in order to substantiate his submissions, places reliance on the judgment of the Supreme court delivered in Appeal (Cri.) 300 of 2001 decided on 16.3.2001 in the case of ***Amery Pharmaceuticals and Anr. vs. State of Rajasthan.***

5. It appears from the contents of the complaints that the respondents Drug Inspector had collected the samples from various Government Hospitals for the purpose of test/analysis. Admittedly, accused Nos. 1 and 2 are partners of accused No.3 M/s. Amrit Pharmaceuticals, having their manufacturing unit at G-5, M.I.D.C. Chikalthana, Aurangabad. Respondent No.2 Drug Inspector drew samples of sodium chloride injection I.P. Batch 3907 L-1. The

manufacturing and expiry dates are given in detail in the above mentioned chart. Respondent No.2 Drug Inspector has sent the samples to the Government Analyst and on receiving the report in respect of each of the sample on various dates, as mentioned in the chart, found that the said sample is not of standard quality for the reason that the sample contained suspended matter visible to unaided eyes. Initially, the test report received from the Government Analyst was sent to the medical store in charge of the concerned Hospitals and on communication from the said hospitals about the manufacturer of the said Drug, the respondent Drug Inspector delivered a copy of the test report of the Government Analyst alongwith one intact sealed portion of the said sample of the batch, as stated above to original accused No.3 Amrit Pharmaceuticals, Aurangabad, by registered post A.D.

6. It is alleged in the complaint that in terms of Section 25 of the the Act of 1940, the respondent Drug Inspector has followed the procedure. It would be appropriate to refer to Section 25 of the Act of 1940, which is reproduced herein below:-

> *"**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 18-A], 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 18-A] 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 controverson 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."

7. In terms of sub-Section (3) of Section 25 of the Act of 1940, if any of the person, who receives copy of the report of the Government analyst fails to notify his intention to adduce evidence in contravention of facts stated in the report within a period of 28 days of the receipt of the report, then such report of the Government analyst become conclusive evidence regarding the facts stated thereunder as against the such person. So far as the accused like manufacturer in the present case is concerned, he can also avail remedy indicated in sub-section (4) of section 25 of the Act of 1940, by requesting the Court to send the other portion of the sample remained in the court, to be tested by Central laboratory. In terms of provisions of sub-section (4) of Section 23 of the Act of 1940 the Inspector shall produce the sample to the Court before which the proceedings, if any, are instituted in respect of the said drugs.

8. In all the cases, on appearance before the trial court, the petitioners herein submitted applications, contending therein that after receipt of copy of the report of Government analyst from the Drug Inspector, the petitioners have notified the Drug Inspector in writing within a period of 28 days under certificate of posting that the report of the Government Analyst was absolutely incorrect and unreliable. The petitioners intended to adduce evidence in

contravention of the said report at appropriate stage of the trial. Such intimation within 28 days given to the respondent Drug Inspector, is detailed in the above chart. Further, the petitioners also brought to the notice of the Court that they intended to adduce evidence in contravention of the said report and since respondent Drug Inspector has not produced the samples before the Court, though mandatory in terms of provisions of sub-section (4) of Section 23 of the Act of 1940, they reserved their right to file an application under sub-section (4) of Section 25 of the Act of 1940 at the appropriate stage of trial. The petitioners accordingly prayed in the said applications that their right to adduce evidence in contravention of the report of Government analyst, be reserved. Learned Magistrate, on such application in each of the complaints, called upon the other side to file their say. However, on careful perusal of the record and proceedings of each and every case, I do not find that the respondent Drug Inspector has filed his say to the applications filed immediately on appearance before the Court in each and every complaint.

9. Further, the petitioners in each and every complaints filed applications for discharge, mainly on the ground that the respondent Drug Inspector has committed serious breach of mandatory provisions of the Act of 1940. It has also brought to the notice of the

Court that Inspite of the requirements of law, the sample bottles have not been produced before the Court. The petitioners also be discharged on the ground that even though they reserved their right to file application under the provisions of sub-section (4) of Section 25 of the Act of 1940, the respondent Drug Inspector has not submitted any of the sample bottles before the court. It was also brought to the notice of the Court that Inspite of the date of expiry referred to above, the respondent Drug Inspector has deliberately avoided to submit the sample bottles in the Court. The petitioners further contended in the said application that their right to lead contrary evidence was taken away fraudulently.

10. Respondent Drug Inspector has filed his say to the said application separately in each and every complaint and contended that no such notification in writing was sent to him by the petitioners herein and further contended that the respondent Drug Inspector is ready to produce the sample, if directed by the court. The respondent Drug Inspector has also contended in the say that the petitioners have not filed any application before the Court in terms of provisions of Section 25(4) of the Act of 1940. It further appears from the record of each and every complaint that afterwards realizing the mistake of not producing the sample before the court, the respondent Drug Inspector has produced the sample almost in the year 1992, in

each and every case.

11. It is a part of record that on appearance before the court, in all the complaints, the petitioners have immediately submitted applications requesting thereby to the court to reserve their right to adduce evidence in contravention of the report of the Government analyst. Even though the learned Magistrate called upon the respondent Drug Inspector to file his say, however, no say was filed to such applications. The petitioners have specifically contended in the said applications the date on which they had notified the Drug Inspector in writing, within a period of 28 days by post that the Government analyst's report was incorrect and unreliable and that they intended to adduce the evidence in contravention to said report at the appropriate time. In the information submitted by the petitioners in the above chart, specific dates are mentioned on which the petitioners gave intimation to the Drug Inspector in terms of sub-section (3) of Section 25 of the Act 1940. In the year 1992, in all the cases, the petitioners when filed applications for discharge on various counts, as discussed above, the respondent Drug Inspector has denied about the receipt of such intimation and to my surprise, also denied the applications filed by the petitioners before the Court in terms of provisions of sub-section (4) of Section 25 of the Act of 1940. It is a part of the record that till the year 1992, the respondent

Drug Inspector has not produced before the court the samples, though it is mandatory on his part to produce the same before the court in terms of sub-section (4) of Section 23 of the Act of 1940. In view of above, the petitioners lost their valuable right to adduce evidence in contravention of Government analyst report.

12. Furthermore, the prosecution came to be launched in each and every case after much delay and just before expiry of the shelf life of the sample. In all the cases, the report of the Government analyst came to be received in the year 1987 itself i.e. during the period from 17.3.1987 to 27.10.1987. However, the prosecution came to be launched from May 1988 onwards in each and every case. On careful perusal of each and every complaint, I find that just before expiry of shelf life of the sample, the complaints came to be filed before the Magistrate. In that way also, there was no propriety as such, to send the sample to the Central Laboratory, when its shelf life was already expired. Furthermore, in order to comply with the provisions of sub-section (4) of Section 25 of the Act of 1940, the samples need to be produced before the Court and the court may, in its discretion, send such samples to the Central laboratory *suo moto* or on the application submitted by the accused.

13. In the case of ***Venkaiah Chowdary Nannapaneni and***

others (supra) relied upon by learned counsel for the petitioners, this Court has made the following observations:-

> *"In cases falling under the Act prompt action at every stage is a must though it is not expressly made clear in the Act. The samples drawn must be sent for analysis forthwith. Portions thereof must be given to the concerned parties without loss of time. Report must be prepared expeditiously. It must be sent to the Inspector with expedition. Copies of the report must be served on the concerned parties as soon as possible and complaint must be lodged without wasting time. Reason for this expedition at every stage is the shelf-life of a drug and the need to get it analysed within a particular time frame. While sub-section (1) of Section 24 of the Insecticides Act 1968, the Insecticide Analyst has to submit his report within a period of 60 days, surprisingly there is no such provision in the Act providing for an outer limit for submission of the report. It is elementary that no complaint could be filed till such time as the report of the analyst is received. If the report is delayed consequently the complaint would be delayed. Delayed complaint may result in denying the accused or the complainant the right to get the samples tested from the Central Drugs Laboratory before the shelf-life of the drug is over. That would frustrate the prosecution. Prompt lodging of the complaint therefore is of prima importance."*

14. In the case of ***M/s. Medicamen Biotech Limited and another vs. High Court of Delhi, Vineeta Goyal vs. Rubina Bose***,, relied upon by learned counsel for the petitioners, the Supreme Court when found that the accused disputed the report and requested for test by

the Central Laboratory and no action was taken thereon and further the complaint filed just few days before expiry of sample drug, petitioners lost the valuable right to get the sample re-tested. The Supreme court in para 10 of the said judgment, made the following observations:-

> *"10. We find that this Judgment helps the case of the appellant rather than that of the respondent because in spite of two communications from the appellant that it intended to adduce evidence to controvert the facts given in the report of the Government Analyst, the fourth sample with the Magistrate had not been sent for re-analysis. The observations in Amery Pharmaceuticals's case (supra) are also to the same effect. We find that the aforesaid interpretation supports the case of the appellants inasmuch they had been deprived of the right to have the fourth sample tested from the Central Drugs Laboratory. It is also clear that the complaint had been filed on the 2nd July 2002 which is about a month short of the expiry date of the drug and as such had the accused-appellant appeared before the Magistrate even on 2nd July 2002 it would have been well nigh impossible to get the sample tested before its expiry. In the affidavit filed to the petition by Dr. D. Rao, Deputy Drugs Controller, and in arguments before us, it has been repeatedly stressed that the delay in sending of the sample to the Central Drugs Laboratory had occurred as the appellant had avoided service of summons on it till 9th May 2005. This is begging the question. We find that there is no explanation as to why the complaint itself had been filed about a month before the expiry of the shelf-life of the drug and concededly the filing of the complaint had nothing to do with the appearance of the accused in response to the; notices which were to be issued by the Court after the complaint had been filed. Likewise, we observe that the requests for*

re-testing of the drug had been made by the appellant in August/September 2001 as would be clear from the facts already given above and there is absolutely no reason as to why the complaint could not have been filed earlier and the fourth sample sent for re-testing well within time. We are, therefore, of the opinion that the facts of the case suggest that the appellants have been deprived of a valuable right under Sections 25(3) and 25(4) of the Act which must necessitate the quashing of the proceedings against them."

15. In the case of ***Municipal Corporation of Delhi vs. Ghisa Ram (supra)*** and ***State of Maharashtra vs. Vasudeo Shivlingappa Takawade (supra),*** relied upon by learned counsel for the petitioners, though the cases falling under the provisions of Prevention of Food Adulteration Act, in the similar set of facts and identical provisions of the Act, the Supreme Court and the Division Bench of this Court, have taken a similar view and held that the valuable right available to the accused, to get the sample analyzed by the Central laboratory, has been lost due to delay in launching the prosecution.

16. In the instant case, the petitioners original accused have lost their valuable right available under Section 25(3) and 25(4) of the Act of 1940. Further, the complaint came to be filed just before expiry of the shelf life of the drug, virtually making it impossible for the

petitioners to exercise their right in terms of provision of Section 25(3) and 25(4) of the Act of 1940. The petitioners are entitled for discharge on this ground alone.

17. In view of Volume No.1 of Indian Pharmacopoeia 1985, as referred in case of ***Narendrakumar vs. State of Maharashtra, (supra)*** relied upon by learned counsel for the petitioners, so far as the drug or injection called "Sodium Chloride and Dextrose" is concerned, it is laid down under the heading "storage" as follows:-

> "Storage" Store in single-dose containers in a cool place. On keeping, small solid particles may separate from glass containers."

Further under the head of labellings it is laid down as follows:- .

> "Labelling.- (I) The label states the strength as the percentages w/v of Sodium Chloride and of Dextrose and (ii) that a solution containing visible particles must not be used."

18. It is thus clear that the said drug is required to be stored in a cool place and as stated in the Indian Pharmacopoeia, the "cool" place means any temperature between 8° and 25°. This position of storage conditions and labelling remained as it is, at least till the year 2014 since the Indian Pharmacopoeia of 2014 is placed before this Court during the course of arguments. It has further made clear that

if solution containing visible solid particles, the same must not be used. There is no dispute that the labelling conditions have been followed by the petitioners, including displaying instructions that solution containing visible particles must not be used. In the instant case, much after manufacturing date, the samples of sodium chloride injection I.P. came to be seized from storage of various hospitals. On careful perusal of the report, I do not find that any foreign material was found in the sample. Thus, development of such particles due to non observance of storage of such drug in a cool place, cannot be ruled out altogether.

19. In the case of ***Narendrakumar vs. State of Maharashtra, (supra)*** relied upon by learned counsel for the petitioners, this Court in identical situation in para 7 of the judgment, made following observations:-

> *"7. Thus the two essential standards or the conditions laid down are that the injection should be stored in a cool place and secondly the injection should not be used if it contains visible solid particles. It therefore, appears that according to the Pharmacopoeia of India the development of visible solid particles is a natural phenomenon during storage if there is variation in temperature, hence label is required to be put on such drugs with the instructions that the injection should not be used if it contains visible solid particles. If the drug in question contained visible solid particles the hospitals ought not to use those injections on the patients. It is not the case of the prosecution that the drug or injection in question contained any foreign material and the ingredients thereof were not in the*

prescribed standard proportion. No samples were taken from the manufacturers directly and as per the complaint which is the subject matter of Criminal Writ Petition No. 975/89 the injections in question were purchased by the St. George Hospital in September 1986 from the distributors M/s. Delpha Drugs and Pharmaceuticals (India) and the samples in question were taken in the month of November, 1986 from St. George Hospital. The development of particles may be due to non-observance of the standard of storage in a cool place. As stated earlier, it is not the case of the prosecution that these particles were foreign material and not of Sodium Chloride or of Dextrose. In the above circumstances, it cannot be said that there was any contravention of the provisions of Drugs and Cosmetics Act by the petitioner-company."

20. The ratio laid down in the above cited case, squarely applies to the facts and circumstances of the present case. In absence of any other finding, the possibility of development of particles in the instant case on account of non following the standard of storage in a cool place by the respective Government hospitals, cannot be ruled out. In the circumstances, it cannot be said that the petitioners have contravened the provisions of the Act of 1940, even accepting the Government Analyst report as it is.

21. The respondent Drug Inspector has alleged in the complaint that the present petitioners are partners of accused No.3 i.e. M/s. Amrit Pharmaceuticals and by virtue of power of attorney, they are

liable to be prosecuted under Section 34 of the Act of 1940. On careful perusal of the copy of deed of partnership and general power of attorney, which is a part of record of the complaints filed by the respondent Drug Inspector, it appears that the other partners executed general power of attorney in favour of the present petitioners, authorizing them to look after the day to day administration of the firm, such as appointment of agents, employees, workers and other persons and to remove them as and when necessary, pay remuneration, wages, bonus, to file suit or application or commence other proceedings, civil or criminal in respect of or arising out of the said business to swear affidavits on behalf of the firm etc. to purchase any property, to borrow loans etc. However, it is nowhere stated in the general power of attorney that the petitioners herein are responsible for the conduct of the business of the firm so far as the production side is concerned.

22. In the case of ***Umesh Sharma and another vs. S.G. Bhakta and others, reported in 2003 Bom.C.R. (Cri.) 1522***, this Court had an occasion to deal with similar question and accordingly, this Court has considered the definition of “Managing Director” as provided under Section 2(26) of the Companies Act, 1956. This Court has also referred the definition of “Manager” as provided under Section 2(24) of the Companies Act, 1956. By referring those two definitions,

this Court has observed that Manager, by virtue of his office, has the management of whole or substantially whole of the affairs of the company, and the Managing Director has to be entrusted with such powers of the management and powers of management are required to be delegated upon the Managing Director either, by an agreement with the company or by resolution passed by the Board of Director in its general meeting or by virtue of its memorandum or article of association. It is not the name by which the person is called, but the position he occupies and the functions and duties which he discharges that determines whether in fact, he is in charge of and responsible to the company or not as defined in Section 2(26) of the Companies Act. Even this Court has distinguished the case in ***U.P. Pollution Control Board Vs. Mohan Meakins Limited and Others, reported in (2000) 3 SCC 745.*** In the said case, there are specific allegations in the complaint by which the Manager or Director of the company can also proceed against when the company, which is alleged to be guilty of the offence. Thus, By referring the two cases of the Supreme Court i.e. ***Municipal Corporation of Delhi Vs. Ram Kishan Rohatagi (supra)*** and State of ***Haryana Vs. Brij Lal Mittal and Others, reported in AIR 1998 SC 2327***, this Court held that in absence of any averment in the complaint that the accused, who is named in the complaint as Managing Director, is responsible and in charge of the entire affairs of company, the process issued against

such an accused is required to be recalled. A similar view is taken by this Court in the cases of ***Narendrakumar Mangilal Dani and Others Vs. State of Maharashtra and another and Venkaiah Chowdary Nannapaneni and Others Vs. State of Maharashtra (supra)***.

23. Though section 34 of the Act of 1940 creates presumption of liability, however, it does not say that the person being merely a partner and in charge of administration of the firm is criminally liable. It is nowhere averred in the complaints that the petitioners are responsible for the objectionable drug and same was manufactured with their consent or in their connivance or production of the said drug is attributed to any neglect on their part.

24. In view of the above discussion and the ratio laid down in the various cases by the Supreme Court and also by the High Courts, I am of the view that the continuation of prosecution in the present case would be a mere formality. Learned Additional Sessions Judge, Aurangabad almost accepted all grounds raised by the petitioners, as discussed above, however, declined to interfere in the order passed by the Magistrate on the ground that these grounds were not at all raised in the applications for discharge before the Magistrate and that the proceedings are pending since more than 14 years. The learned

Additional Sessions Judge has declined to interfere in the order passed by the Magistrate on the ground that all these scientific aspects can be looked into during the course of trial. Thus, the approach of the Courts below is not proper, correct and legal. The petitioners are therefore, entitled for discharge. Hence, I proceed to pass the following order:-

O R D E R

I. All criminal writ petitions are hereby allowed.

II. The common order dated 13.8.2001 passed below Exh.43 in R.C.C. No 1144 of 1997, Exh.39 in R.C.C. No 1145 of 1997, Exh.42 in R.C.C. No 1146 of 1997, Exh.43 in R.C.C. No 1147 of 1997, Exh.23 in R.C.C. No 1148 of 1997, Exh.39 in R.C.C. No 1149 of 1997 (State (Drug Inspector vs. Shankarlal and others) by the learned Chief Judicial Magistrate, Aurangabad and the common judgment and order passed by the Additional Sessions Judge, Aurangabad dated 17.10.2002, in Criminal Revision Nos. 203 of 2001, 204 of 2001, 205 of 2001, 206 of 2001, 207 of 2001 and 211 of 2001, confirming thereby the order passed by the Chief Judicial Magistrate, are hereby quashed and set aside.

III. The application Exh.43 in R.C.C. No. 1144 of 1997, application Exh.39 in R.C.C. No. 1145 of 1997,

application Exh.42 in R.C.C. No. 1146 of 1997, application Exh.43 in R.C.C. No. 1147 of 1997, application Exh.23 in R.C.C. No. 1148 of 1997 and application Exh.39 in R.C.C. No. 1149 of 1997, are hereby allowed and the petitioners herein are discharged for the offences committed under Sections 18 (1) (a) punishable under Sections Sections 27 and 34 of the Drugs and Cosmetics Act 1940.

IV. Rule is made absolute in the above terms

V. Writ petitions are disposed of accordingly.

(V. K. JADHAV, J.)

rlj/