IN THE HIGH COURT OF BOMBAY AT GOA

CRIMINAL APPEAL NO. 14 of 2014

State of Goa,
At the instance of
Mrs. Jyoti Sardessai (Major)
Director of Food and Drugs
Administration,
Old I.P.H.B. Complex
Altinho, Panaji, Goa .. Appellant

V/s

1. M/s Caryl Pharma
61, 5th Main, Brindavan Extension,
Arakere, Mice Layout,
Bannerghatta Road,
Bangalore- 580078,
Represented by its Sole Proprietor,
Shri G. P. Pillai (Major)

2. Shri. G. P. Pillai (Major)
Proprietor of
M/s Caryl Pharma,
61, 5th Main, Brindavan Extension,
Arakere, Mice Layout,
Bannerghatta Road,
Bangalore-580078

3. M/s Ce-Chem Pharmaceuticals,
No.336,IV Phase, Peenya Industrial
Area, Bangalore-580058,
Represented by its Sole Proprietor,
Shri. M. Chandrashekhar (Major)

4. Shri. M.Chandrashekhar, (Major)
Sole Proprietor of
M/s Ce-Chem Pharmaceuticals,
No.336, IV Phase, Peenya Industrial
Area, Bangalore-580058 .. Respondents

Mr. S. R. Rivankar, Public Prosecutor for the appellant.

Mr. S. D. Lotlikar, Senior Advocate with Mr. C. Padgaonkar, Advocate for the respondents.

CORAM :- **C. V. BHADANG, J.**

Date :- 22nd July, 2015.

ORAL JUDGMENT :

By this appeal, the State is challenging the acquittal of the respondents from an offence punishable under Section 18(a)(I) read with Section 27(d) of the Drugs and Cosmetics Act,1940 (the Act, for short).

2. Brief facts are that PW1 Mrs. Jyoti Sardessai, who is the complainant in this case, and a Drugs Inspector, had visited the premises of M/s. Matrix Pharma, Ponda, Goa on 14/01/2004 and collected the sample of a medicine 'Caryrox', Batch No.C202, which is a patent and proprietary medicine. It is a suspension of a generic drug 'Roxithromycin'. The drug was manufactured by the respondent no.3 of which the respondent no.4 is a proprietor under loan license from the respondent no.1, of which the respondent no.2 is a proprietor. The manufacturing date of medicine is July, 2002 and the expiry was shown as June 2004. According to the prosecution, the sample was collected as per the

established procedure. When the sample was sent for analysis by the State Laboratory in Goa, it was found that it was substandard. It may be mentioned that as per the label on the medicine, every 5 ml of the medicine was to contain 50 mg of Roxithromicin. As against this, the State Analyst's report (Exhibit 25) dated 28/04/2004, found that the sample was containing 39.04% of the medicine. In this case, admittedly, the sample was also referred at the instance of the respondents to the Central Drugs Laboratory (CDL), Calcutta and the report from the CDL, Calcutta dated 05/07/2004 is there on record at Exhibit 39, which shows the percentage of the medicine as 31.86%. In such circumstances, a complaint came to be lodged against the respondents for the offences as aforesaid, before the learned Judicial Magistrate, First Class at Ponda.

3. At the trial, the prosecution examined in all four witnesses, namely PW1 Jyoti Sardessai, PW2 Vishwanath, who is the proprietor of M/s. Matrix Pharma and a chemist, PW3 Mohammad Khalid Ahmed Khan and PW4 Bimol Mandal, who is from CDL, Calcutta. There was no defence evidence led on behalf of the respondents, except production of a test certificate dated 09/08/2002, by which the sample was got examined through a private Lab, namely, Strides Arcolab Ltd. The contents of each 5

ml was found to contain 48.4 mg of Roxithromycin. This was produced in order to show that in fact the medicine conforms to the required standard and no offence was made out.

4. The learned Magistrate found that while getting the sample analysed, the manufacture's standards were not ascertained and followed. Secondly, it was found that there was no acceptable evidence that the medicine was stored under standard conditions as required and thirdly that the sample was analysed at the fag end of the expiry period, which was June 2004. In such circumstances, the learned Magistrate found that two views are possible and the one in favour of the respondents has to be preferred. In that view of the matter, the learned Magistrate acquitted the respondents by giving benefit of doubt. Feeling aggrieved, the State is before this Court.

5. I have heard Shri Rivankar, the learned Public Prosecutor for the appellant and Shri Lotlikar, the learned Senior Counsel for the respondents. With the assistance of the learned Counsel, I have perused the entire evidence and the record as also, the impugned judgment.

6. It is submitted by Shri Rivankar, the learned Public

Prosecutor that at the instance of the respondents, the sample was referred to the CDL, Calcutta under Section 25(4) of the Act. It is submitted that once this is done and the accused opts for sending the sample to the CDL, Calcutta, the report from the CDL, Calcutta is conclusive and incontrovertible. Reliance is placed on the decision of the Hon'ble Supreme Court in the case of ***Amery Pharmaceuticals and another Vs. State of Rajasthan***, reported in (2001)4 SCC 382, in order to submit that now the respondents cannot challenge the contents of the report (Exhibit 39) on the ground that the manufacture's standards were not ascertained or followed. It is next submitted that as per the standard storage conditions, mentioned on the carton, the medicine was to be stored in a 'cool place'. The learned Public prosecutor has referred to Note I to Schedule P of the Drugs and Cosmetics Rules, 1945 (the Rules, for short), in order to show that the term 'cool place' means the place having temperature between 10^{o}c and 25^{o}c. It is submitted that the evidence led by the prosecution would show that at the time when the sample was seized i.e. in the month of January, the normal temperature in Goa does not exceed 25^{o}c and thus, even assuming that the sample was stored at room temperature, it cannot affect its stability or the composition. It is next submitted that the mere fact that the sample was analysed at the fag end of the validity period, cannot

come to the aid of the respondents, in as much as the medicine has to conform to the requisite composition till the expiry date. It is submitted that the report of the State Analyst is dated 28/04/2004, which is well before the expiry date, which is June 2004. Even so far as the report of the CDL, Calcutta is concerned PW4 has stated that the sample was analysed before the expiry date. It is submitted that thus, the finding recorded by the Magistrate holding that two views are possible and giving benefit of doubt to the respondents, is clearly perverse and an impossible view, which needs interference by this Court.

7. On the contrary, it is submitted by Shri Lotlikar, the learned Senior Counsel for the respondents that the scope of the interference in an appeal against acquittal is limited. It is submitted that unless and until the finding recorded by the Magistrate is found to be either perverse or based on no evidence or reached on a gross misappreciation of the evidence, no interference is called for. It is submitted that the view taken by the Magistrate is a plausible view. It is next submitted that the prosecution witnesses have admitted that the medicine was susceptible to changes in temperature, humidity as also light. Thus, acceptable evidence about the medicine having been stored in proper storage conditions was necessary. It is submitted that

PW1 has admitted that the medicine was stored at room temperature and thus, it is not possible to hold that the medicine was stored under standard conditions. It is submitted that the Drugs Consultative Committee (DCC) set up under Section 7 of the Act has prescribed the standard procedure for analysis of the pharmaceuticals preparations. The learned Magistrate has relied upon Item No.7 of the guidelines in the minutes of meeting dated 24th and 25th June, 1974, in order to hold that it was necessary to analyse the sample in relation to the manufacture's standards, which were registered with the concerned Drug Controller, Karnataka. That admittedly having not done, the prosecution cannot rely on the evidence of the analyst. He, therefore, submitted that the appeal is without any merit.

8. On hearing the learned Counsel for the parties and on perusal of the record, I do not find that any case for interference is made out. In the present case, admittedly, the respondents are the manufacturers of the drug 'caryrox', which is a patent and proprietary medicine. It is further an admitted position that 'caryrox' is a suspension of the generic drug 'Roxithromicin'. It is further undisputed that each 5 ml of the medicine was to contain 50 mg of 'Roxythromicin B.P.' It is also an admitted position that the said product does not find place in Indian Pharmacopeia, but is

a medicine listed in British Pharmacopeia (BP). The instructions mentioned as to storage are that the medicine is to be stored in a 'cool place', protected from light. It is further undisputed that the manufacturing date of the product is July 2002 and the expiry date was June 2004. A perusal of the Note 1 to Schedule P of the Rules, would show that the term 'cool place' means a place having temperature between 10°c and 25°c . Thus, it can be seen that the standard storage conditions as to temperature for the said product require that it should be stored at a temperature between 10°c and 25°c . PW1 Jyoti Sardessai, who is a material witness, has stated in the cross-examination that at the time of visit to the premises of M/s. Matrix Pharma, she had not taken any gadget, instrument or machine for the purpose of taking reading and measurements pertaining to the temperature, humidity, etc. She has also admitted that the premises, where the drug was stored, was not air-conditioned. She could not say what was the temperature at the premises of M/s Matrix Pharma at the time of her visit, although she volunteered that it was cool. She then stated that the average temperature in Goa specially in the month of June and July ranges from 23 to 32°c and at times goes upto 34°c. She has further admitted that the exposure to heat has a detrimental effect on the stability of pharmaceutical products and medicines. It was stated that with every 10 degrees rise in the

temperature, there is possibility of 2 to 3 fold increase in degradation rates of the drugs. She has stated that in respect of the drugs, which are sensitive to heat, there is possibility of such variation.

It can, thus, be seen that it has sufficiently come on record that the drug was sensitive to temperature variations and as per the standard conditions, it was supposed to be stored at a temperature between 10°c and 25°c . It is not possible to take a judicial notice of the temperature, which prevails at a particular place and that too, at the time when the sample was collected. That apart, it is not only the time when the sample was collected which would be relevant, as the medicine has to conform to the required standard and, therefore, during the entire validity period, is required to be stored in standard condition as to the humidity, light and temperature, during the period of its validity i.e. till the expiry date. For this reason, it is not possible to accept that at the time when the sample was taken PW1 says that it was 'cool'. There has to be acceptable evidence on record to show that indeed the medicine was stored under standard conditions. The prosecution had examined PW2 Vishwanath, who is a proprietor of M/s. Matrix Pharma from where the sample was collected. He was the best witness, who could have deposed that the medicine was stored under standard conditions as required. However, that

evidence is not forthcoming. This witness was cross-examined at length and he has admitted that the said drug was to be stored at a cool place, protected from light. He admitted that only certain drugs can be stored at room temperature. If that be so, certainly the drug, in the present case, could not have been stored at room temperature. As has been admitted by PW1, the composition of the drug is susceptible to variation and change with the variation of the temperature.

9. It is true that under Section 25(4) of the Act, once the accused opts for sending sample to the CDL, Calcutta, conclusiveness would attach to the report of the CDL, Calcutta However, the question is whether such deterioration, as has been noticed either by the State Anaylist or the CDL, Calcutta, was on account of a defect at the stage of manufacture or was as a result of drug being stored under improper storage conditions. Certainly, on that count, there is no acceptable and satisfactory evidence forthcoming from the prosecution that the drug was stored under standard conditions, as required. There is one more aspect. Admittedly, the manufacture's standards were not ascertained or followed at the time of analysis in this case. PW4 has stated in his cross-examination that the manufacture's procedure of testing the sample was asked for, however, for want

of sufficient time, as the expiry date was approaching, he could not wait till the procedure was received. The learned Magistrate has considered this as one of the reasons for extending the benefit of doubt.

10. I have given my anxious consideration to the reasons articulated by the learned Magistrate in holding that the respondents are entitled to a benefit of doubt in this case, as two views are possible. I do not find that the view taken can either be said to be perverse or an impossible view. The appeal is, therefore, without merit and is accordingly, dismissed.

C. V. BHADANG, J.

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