



CrI.O.P.No.8095 of 2024
& CrI.M.P.No.5897 of 2024

IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 23.04.2024

Pronounced on: 30.04.2024

Coram:

THE HONOURABLE Dr. JUSTICE G.JAYACHANDRAN

CrI.O.P.No.8095 of 2024
& CrI.M.P.No.5897 of 2024

1. M/s.Medybiz Pharma Pvt. Ltd., (A-1),
No.8/28, Madurai Veeran Kovil Street,
T.Nagar, Chennai – 600 017.
Represented by its Director,
Thiru.Koneti Aswin Kumar Madhan Babu.

2. Thiru.Koneti Aswin Kumar Madhan Babu, (A-2).
Director of M/s.Medybiz Pharma Pvt. Ltd.,
No.8/28, Madurai Veeran Koil Street,
T.Nagar, Chennai – 600 017.

.... Petitioners/Accused

/versus/

The State of Tamil Nadu represented by:-
The Drug Inspector,
T.Nagar Range,
O/o.The Assistant Director of Drugs Control Zone-II,
DMS Campus, No.359, Anna Salai,
Teynampet, Chennai – 600 006.

.... Respondent/Complainant

Prayer:- Criminal Original Petition has been filed under Section 482 of Cr.P.C., to call for the records in C.C.No.1047 of 2022 pending for trial on the file of the Learned IV Metropolitan Magistrate, Saidapet, Chennai and quash the same as against the petitioners.



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For Petitioners : Mr.K.Madhan

For Respondent : Mr.K.M.D.Muhilan
Government Advocate (CrI.Side)

ORDER

The Drug Inspector, T.Nagar Range has filed a complaint under Section 18 (c) r/w Rule 65 (9) (b) of the Drugs and Cosmetic Act 1940 against the petitioners herein and others for selling schedule H-Drugs to registered medical practitioners without obtaining the signed order in writing and for not mentioning the address of the licensee to whom the Drugs were sold and the license number of the purchaser which is an offence punishable under Section 27(d) of the Drugs and Cosmetic Act, 1940.

2. As per the complaint on 15.03.2018, the Drug Inspector inspected the premises of M/s.Medybiz Pharma Pvt Ltd at T.Nagar, Chennai. During the course of inspection, Mr.V.Balaji (A3) was present and he is the competent person appointed by M/s.Medybiz Pharma Pvt Ltd. During the inspection the following drugs which were already sold by M/s.Medybiz Pharma Pvt Ltd were not purchased with purchase invoices and sold without the license number of the buyer as follows.



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Sl. No.	Name of the Drug	Batch No.	Sale Bill No. and dated	Qty sold	To whom drug sold
1.	Remicade 100 mg Inj	HBM94014A	1700284001349 dated 01.03.2018	7	Get fast pharmaceuticals Private Limited, Nungambakkam, Chennai.
2.	Remicade 100 mg Inj	HCM05015	1700284001349 dated 01.03.2018	8	Get fast pharmaceuticals Private Limited, Nungambakkam, Chennai.
3.	Imbruvica Caps 90's pack	481276	1700284001283 dated 08.02.2018	1	Get fast pharmaceuticals Private Limited, Nungambakkam, Chennai.
4.	Imbruvica Caps 90's pack	481402	1700284001283 dated 08.02.2018	4	Get fast pharmaceuticals Private Limited, Nungambakkam, Chennai.
5.	Imbruvica Caps 90's pack	481276	1700284001188 dated 28.12.2017	1	Medybiz Pharma Pvt Ltd.
6.	Juvederm voluma with lidocaine	VB20A70515	17002830069 dated 22.01.2018	2	Dr.Gayathri, Chennai – 42.
7.	Juvederm voluma with lidocaine	VB20A70515	17002830071 dated 27.01.2018	2	Dr.Gayathri, Chennai – 42.
8.	Juvederm voluma with lidocaine	VB20A70603	17002830088 dated 23.02.2018	1	Dr.Gayathri, Chennai – 42.
9.	Juvederm Voluma with lidocaine	V17LA70472	17002830088 dated 23.02.2018	2	Dr.Gayathri, Chennai – 42.



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Thus, there is a contravention of Section 18 (c) read with Rule 65

(5)(1)(3) of the Drugs and Cosmetic Act, 1940.

3. The show cause notice was issued calling for particulars from M/s.Medybiz Pharma Pvt Ltd. Based on the information furnished by M/s.Medybiz Pharma Pvt Ltd, M/s.Johnson & Johnson Pvt Ltd which has supplied those drugs to M/s.Medybiz Pharma Pvt Ltd was called for explanation. Being satisfied that M/s.Medybiz Pharma Pvt Ltd and its Directors through competent person had violated Section 18 (c) r/w Rule 65 (9) (b) of Drugs and Cosmetic Act by selling the following H-schedule Drug to registered Medical practitioners without obtaining the signed order of the purchaser, hence liable to be prosecuted.

<i>Sl. No.</i>	<i>Name of the Drug</i>	<i>Batch No.</i>	<i>Sale Bill No. and dated</i>	<i>Qty sold</i>	<i>To whom drug sold</i>
1.	Juvederm voluma with lidocaine	VB20A70515	17002830069 dated 22.01.2018	2	Dr.Gayathri, Chennai - 42.
2.	Juvederm voluma with lidocaine	VB20A70515	17002830071 dated 27.01.2018	2	Dr.Gayathri, Chennai – 42.
3.	Juvederm voluma with lidocaine	VB20A70603	17002830088 dated 23.02.2018	1	Dr.Gayathri, Chennai – 42.



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Sl. No.	Name of the Drug	Batch No.	Sale Bill No. and dated	Qty sold	To whom drug sold
4.	Juvederm Voluma with lidocaine	V17LA70472	17002830088 dated 23.02.2018	2	Dr.Gayathri, Chennai – 42.

4. The complaint was lodged against six accused, including the supplier of M/s.Johnson and Johnson Pvt Ltd, its Managing Director and authorised signatories. However, the case against the manufacturer who supplied the medicine to the dealer, M/s.Medybiz Pharma Pvt Ltd, was quashed by this Court *vide* order dated 26.07.2023 in CrI.O.P.No.30273 of 2024 holding that the change of address of M/s.Medybiz Pharma Pvt Ltd from Rajamannar Street, T.Nagar, Chennai to Madurai Veera Koil Street, T.Nagar, Chenani will not attract offence under the Drugs and Cosmetics Act. Therefore, the sanction to prosecute without application of mind is bad in law.

5. The present petition is filed by M/s.Medybiz Pharma Pvt Ltd and its Director who are arrayed as A1 & A2 on the ground that the delay in filing the complaint beyond three years is hit by law of limitation under Section 468 of Cr.P.C. According to the prosecution, inspection was made on 15.03.2018 and the document regarding signed order of the purchasers was



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sought to be produced within a week. While so, after the expiry of week time, the limitation to prosecute commences. The offence alleged to have been committed by these petitioners attracts maximum sentence of two years. Whereas, the complaint which ought to have been filed within a period of three years from the date of offence been filed only in the month of April 2022, after four years and one month. Thus, there is a delay of more than one year in filing the complaint. Hence, the prosecution is liable to be quashed.

6. The complaint indicates that the sanction to prosecute was obtained on 23.06.2021 for the offences prescribed under Chapter IV of Drugs and Cosmetic Act. No sanction to prosecute is required and therefore, there cannot be any exemption of time limit for the delay in getting sanction. The show cause notice does not call for any signed order copy for the drugs sold. Whereas, the petitioners are prosecuted for not producing the signed order copy of the purchasers. Thus, violation of Section 18 (c) r/w Rule 65(5)(1)(3) of Drugs and Cosmetic Act, 1940 and Rules 1941.

7. The 2nd petitioner is the Director of the Company. He resides at Bangalore and he is not administering the day-to-day affairs of the A1-



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Company. Admittedly, the premises was under the personal supervision of the competent person, namely, V.Balaji (A3). Therefore, the Director of the Company cannot be held vicariously liable for criminal prosecution, when there is no material to show that he had control over the day-to-day affairs of the Company.

8. The Learned Government Advocate (Crl.Side) appearing for the respondent/state would submit that the sanction to prosecute does not contemplated under the Drugs and Cosmetic Act for the offence under Chapter IV of the said Act. The Tamil Nadu Medical Code mandates sanction by appropriate authority to prosecute under the Act and therefore, the sanction to prosecute the petitioners was sought by the Drug Inspector on 09.03.2021. The sanction was accorded on 01.07.2021. The period for obtaining sanction has to be excluded while reckoning the limitation. Therefore, the prosecution is well within the period of limitation.

9. Regarding the alleged defect in the show cause notice, the Learned Government Advocate (Crl.Side) for the respondent states that it is incorrect to say that the person competent was not asked to furnish the signed



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order in writing. Referring the spot memo issued on the day of inspection, the Learned Government Advocate (Crl.Side) for the respondent submitted that the competent person was asked to produce the following items including signed order copy in writing from the registered medical practitioners from 20.11.2017 to 15.03.2018 as below:-

1. Original drug license in form 20B 7 21B

2. Purchase invoices

(i). 170158400464, dated 13.03.2018

(ii). MH0011000340, dated 04.03.2018.

(iii). 4122002060, dated 24.11.2017.

(iv). 4122002873, dated 25.01.2018.

(v). 4122002874, dated 25.01.2018.

3. Sale bill carbon copies from 20.11.2017 to 15.03.2018.

4. Signed order copy in writing from registered medical practitioner from 20.11.2017 to 15.03.2018.

10. Regarding the plea of vicarious liability does not applicable to criminal law, the Learned Government Advocate (Crl.Side) for the respondent referring Section 34 of the Drugs and Cosmetic Act which deals with offence by Companies submitted that the 1st petitioner as a Company and the 2nd



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petitioner as its Director liable for the offence committed since the offence of selling H-Schedule Drug without written signed order was well within their knowledge and it is the burden of the petitioners to disprove the same during the trial.

11. The learned Counsel for the petitioners in support of his argument rely upon the following judgments.

(i). *Y.V.S & Co. and others -vs- The State* reported in *2022 (3) MLJ (CrI) 465*.

(ii). *Lalankumar Singh and Ors. -vs- State of Maharashtra* reported in *AIR 2022 SC 5151*.

(iii). *Crescent Therapeutics Limited and Ors -vs- Union of India* reported in *2024 (1) MLJ (CrI) 107*.

12. In this case, the plea of limitation is not in favour of the petitioners since obtaining sanction from the competent authority is mandated under the Tamil Nadu Medical Code, though not under the Drugs and Cosmetics Act. The Drug Inspector, who is a public servant under the Tamil Nadu Medical Code, which has to be read as an ancillary subordinate legislature to the Drugs and Cosmetics Act, thus it cannot be ignored. That



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apart, the Trial Court having taken cognizance of the offence, it has to be presumed that it has taken judicial notice of the moratorium issued by the Hon'ble Supreme Court in view of the pandemic situation for reckoning limitation. If that period is excluded between March 2020 and April 2021, the complaint will be well within the limitation.

13. Regarding the plea of failure to call for documents relating to the signed order of the purchasers from the spot inspection memo dated 15.03.2018, it is clear that the competent person by name, V.Balaji (A3) been informed to produce the signed order copy in writing from the registered medical practitioners for the period 20.11.2017 to 15.03.2018, which was admittedly not furnished.

14. However, this Court also find that on 06.11.2019 show cause notice memo was issued to the Company's address in Bangalore calling for certain details for the purpose of investigation, wherein there is no allegation of selling H-schedule drugs without written order. In this show cause notice, it is alleged that the drugs mentioned in the table were not purchased with purchase invoice and the details of Drugs already sold without invoice are in



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contravention of Section 18(c) r/w Rule 65 (5)(1)(3) of the Drugs and Cosmetics Act. In the same show cause notice, the Company has been asked to furnish particulars within 5 days from the date of receipt of the notice or else appropriate legal action will be taken without further notice. The particulars sought from the Company are as below:-

1. Constitution of the firm with. relevant document like Memorandum and articles of association to be submitted.

2. Name, age, father's name, residential address, permanent address of Directors/Managing Director/s to be submitted.

3. Name, age, father's name, residential address, permanent address, phone numbers and cell numbers of the person or persons responsible for the conduct of the business of the company at M/s.Medybiz Pharma Pvt. Ltd., 8/28, Madurai Veeran Kovil Steet, T.Nagar, Chennai -17.

15. This Court, therefore finds that though in the spot memo there is a reference for production of signed order in written from the registered medical practitioners, the spot memo was issued to the competent person namely, V.Balaji (A3). When the show cause notice issued to the Company



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which is the petitioners herein, there is no such notice for production of signed order copy of the purchasers.

Section 18(c) of the Drugs and Cosmetics Act, 1940 prohibits:-

18. Prohibition of manufacture and sale of certain drugs and cosmetics.

(a).....

.....

(c). manufacturer for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a license issued for such purpose under this Chapter.

Rule 65(9)(b) of the Drugs and Cosmetics Act deals with:-

65. Conditions of licenses.

(9).

(b). The supply of Drugs specific under Schedule H and Schedule H(1) or Schedule X to registered medical Practitioners, Hospitals, Dispensaries and Nursery Homes to be made only against the signed order in writing which shall be preserved by the licensee for a period of two years.



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16. Since there is no show cause notice issued to the Company for production of signed order for selling H-schedule Drugs, this Court is of the view that the prosecution against the Company without giving adequate opportunity to defend the charge, is bad in law.

17. Therefore, though the other two points raised by the Learned Counsel for the petitioners may not be a good reason to quash the complaint, the prosecution for an offence which does not form part of the show cause notice before lodging the complaint renders the prosecution illegal.

18. Hence, the petition to quash the complaint in C.C.No.1047 of 2022 on the file of the Learned IV Metropolitan Magistrate, Saidapet, Chennai is hereby allowed. Accordingly, this Criminal Original Petition is Allowed. Consequently, connected Miscellaneous Petition is closed.

30.04.2024

Index :Yes
Internet :Yes.
Speaking Order/Non-speaking order
bsm



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Copy to:-

1. The IV Metropolitan Magistrate, Saidapet, Chennai.
2. The Drug Inspector,
T.Nagar Range,
O/o.The Assistant Director of Drugs Control Zone-II,
DMS Campus, No.359, Anna Salai,
Teynampet, Chennai – 600 006.
3. The Public Prosecutor, High Court, Madras.



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DR.G.JAYACHANDRAN, J.

bsm

Pre-delivery order made in
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