BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

Reserved on: 23.11.2017
Delivered on: 06.06.2018

CORAM:

THE HONOURABLE MR.JUSTICE S.S.SUNDAR

CRL.OP.(MD)Nos.10853 and 11883 of 2017
and
CRL.M.P.(MD)Nos.7428, 7429, 8171 and 8172 of 2017

CRL.OP.(MD)No.10853 and 11883 of 2017:-

M/s.Proctor & Gamble Hygiene
and Health Care Limited,
Toll Logistics, Chennai,
represented by K.Chandrasekar
Legal Advisor and Authorized Power of Attorney.
:Petitioner in CRL.OP.(MD).No.10853 of 2017

Shantanu Khosla :Petitioner in CRL.OP.(MD).No.11883 of 2017

Vs.

State represented by
Drugs Inspector,
Trichy II Range,
Trichy Zone, Trichy - 620 018. ... Respondent in both cases

Prayer in CRL.OP.(MD).No.10853 of 2017: Criminal Original Petition is filed under Section 482 of Criminal Procedure Code, to call for the records connected in C.C.No.217 of 2015 on the file of the Judicial Magistrate Court No.1, Trichy and quash the same as far as the petitioner/Accused No.4 (wrongly shown as Accused No.5 in the impugned complaint) is concerned.

Prayer in CRL.OP.(MD).No.11883 of 2017: Criminal Original Petition is filed under Section 482 of Criminal Procedure Code, to call for the records connected in C.C.No.217 of 2015 on the file of the Judicial Magistrate Court No.1, Trichy and quash the same as far as the petitioner/accused No.5 (wrongly shown as Accused No.6 in the impugned complaint) is concerned.

For Petitioners in both cases : Mr.C.Saravanan
for Mr.S.Sukumar

For Respondent in both cases : Mr.K.S.Durapandian
Additional Public Prosecutor

COMMON ORDER

The above criminal original petitions have been filed to quash the proceedings in C.C.No.217 of 2015 on the file of the Judicial Magistrate Court No.1, Trichy, insofar as the petitioners in these criminal original petitions are concerned, who are the accused Nos.4 and 5.

2.The petitioner in Crl.O.P.(MD)No.10853 of 2017, who is the fourth accused in C.C.No.217 of 2015 on the file of Judicial Magistrate Court-No.1, Trichy and the petitioner in Crl.O.P.(MD)No.11883 of 2017, is the accused No.5 in C.C. No.217 of 2015 on the file of Judicial Magistrate Court-No.1, Trichy.

3.The brief facts that are necessary for the disposal of these criminal original petitions are follows:

3.1.The respondent in these cases, is the State represented by Drugs Inspector, Trichy II Range, Trichy Zone, Trichy. The respondent has lodged a complaint against the petitioners and others under Section 32 of Drugs and Cosmetics Act, 1940, for the contravention of Section 18(c) of the Act r/w Rule 65 with condition of licence in Form 20-B of the Drugs and Cosmetics Rules 1945, which are punishable under Sections 27(b)(ii), 28 and 27(d) of the Act.

3.2.It is stated in the complaint that the complainant along with other officials caused a joint inspection on 30.12.2013, at M/s.Solaimalai Enterprises, D.No.19/2A, Chennai By-Pass Road, near Esskay Petrol Bunk, TVS Tollgate, Trichy, the premises of the first accused, and found that the drugs manufactured and supplied by the fourth accused, were stocked in the said premises without valid drug licence. After getting sanction for prosecuting the accused, the complainant has stated that the petitioners in these petitions, namely, M/s.Proctor & Gamble Hygiene and Health Care Limited and the then Managing Director, Thiru.Shantanu Khosla, namely, the accused Nos.4 and 5 had contravened Section 18(c) of the Drugs and Cosmatics Act, 1940, r/w Rule 65(C), r/w condition of licence stated in clause 3(ii) of Form 20B for having sold the subject drug to the unlicenced dealer, the first accused, namely, M/s.Solamalai Enterprises, at D.No.19/2A, Chennai By-Pass Road, near Esskay Petrol Bunk, TVS Tollgate, Trichy, which is punishable under Section 27(B) of the Act.

3.3.Though the case was registered in 2015, the petitioners have filed the above petitions only in 2017. Going by the complaint, the facts are very simple that the petitioners in these petitions were charged for the offences punishable under the provisions of Drugs and Cosmetics Act, 1940, for selling goods to the first accused, who is not holding requisite licence to sell or

stock or exhibit for sale or distribute the drug. However, the petitioners in these petitions filed the above petitions to quash the proceedings.

4.The primary submission of the learned Counsel for the petitioners is that the petitioner company is a well known manufacturer of several drugs and cosmetic products under a valid licence. It is the specific case of the petitioners in both cases that the company had manufactured the drug (Vicks Action 500 Extra) under valid loan licence arrangement from the factory belonging to M/s.Sarvotham Remedies Limited, Himachal Pradesh. It is further stated in the petition that as a manufacturer of the drugs, under loan licence arrangement, the petitioner company has obtained loan licence in Form 25-A, to manufacture and sell Vicks Action 500 Extra (for brevity, herein after referred to as drug). The said licence is valid and subsisting.

5.It is the case of the petitioners that M/s.Solaimalai Enterprises, namely, the first accused, which is represented by one Thiru P.Pitchai, the second accused was appointed as sole distributor of the petitioner company for the whole State of Tamil Nadu except Kancheepuram District, Tiruvalluvar District and the City of Chennai. It is further contended that the Distributor M/s. Solaimalai Enterprises, the first accused in this case, had several warehouses and was a registered dealer under the Drugs and Cosmetics Act, 1940. Though it is admitted that the petitioner company's dealer M/s.Solaimalai Enterprises, had licence as per Rule 61(1) of the Drugs and Cosmetics Act, 1940, in respect of different premises, at the time of inspection in the premises, the first accused did not have a valid licence under Form 20-B. It is described as a mistake of the petitioner company and that it is contended that this mistake have been rectified later by the first accused by obtaining a licence under Form 20-B. Therefore, there is no serious offence committed even by the dealer.

6.It is the prime contention of the petitioners in both cases that as a manufacturer of the Drug under loan licence arrangement, the petitioner company is only bound by the conditions specified under Form-25-A. Rule 70A of the Drugs and Cosmetics Rule, 1945 and Rules 61 and 65 of the Drugs and Cosmetics Rule, 1945, and Section 27(d) of Drugs and Cosmetics Act, 1940 are not applicable to the petitioners in both cases. It is further contended by the learned Counsel for the petitioners that the erstwhile Managing Director of the Company, the fifth accused seems to be an employee of the fourth accused and as Managing Director of the company, he was concerned with the corporate affairs at the Head Office of the Company and not concerned with the day today business affairs of the Company. It is further stated that Rule 61 r/w 65 of Drugs and Cosmetics Rules, 1945, are applicable only to dealers, like the first accused and that therefore, there is no scope for making

manufacturer vicariously liable for the mistake, if any that was committed by the distributors of dealers or retailers. It was further contended by the learned Counsel for the petitioner in both cases that selling or stocking for selling without proper licence might have been violated by the dealer and that for the mistake or irregularity committed by the dealer, the petitioner in both cases cannot be made liable.

7.It was further pointed out by the learned Counsel for the petitioner in both cases that samples were taken for analysis under Form-17, dated 30.12.2013 and sent to Government Analyst (Drugs), Drugs Testing Laboratory, Chennai under Form-18, dated 30.12.2013. By referring to the report of the Government Analyst, dated 10.03.2014, vide Form-13, the learned Counsel for the petitioner in both cases further submitted that the learned Judicial Magistrate No.I, Trichy, has directed the complainant to handover the seized drugs to the third accused, after finding that the analyst has reported that the samples taken were of standard quality. When the manufacturer has not committed any irregularity, it is submitted by the learned Counsel for the petitioner in both cases that the provisions of Rules 61 and 65 are not applicable to the petitioner in both cases as they are not traders or Distributors. It is also submitted that invocation of Section 27 (d) of Drugs and Cosmetics Act, 1940 is without any legal or factual basis.

8.The learned Counsel then submitted that the petitioner in Crl.O.P.(MD)No.11883 of 2017 is only a former Managing Director of the Company, namely, the fourth accused and that he cannot be made liable, unless it is shown or proved that the petitioner is the person, who is incharge of the business of the Company. The learned Counsel for the petitioner also relied upon few precedents for the proposition that the complaint against the Managing Director in a representative capacity without alleging his actual role which prompted the complainant in implicating him would not stand.

9.In both cases, the prime contentions of the learned Counsel for the petitioner is that Rules 61 to 65 of Drugs and Cosmetics Rules, 1945, are not applicable to the manufacturer. The learned Counsel for the petitioner in both cases has referred to Form-25 (A), which is applicable to the manufacturer and submitted that there is no violation of any of the conditions of the licence that was granted to the petitioner company. It was therefore, contended that invocation of Section 27(D) of the Drugs and Cosmetics Act, 1940, r/w, 61 of Drugs and Cosmetics Rules, 1945, is unsustainable, as there is no legal or factual basis in the complaint as against the petitioner in both cases.

10.The respondent/complainant filed a counter affidavit, stating that the Company, namely, the fourth accused is having a

wholesale drug licence under Forms 20B and 21B at D.No.117, 118/1, 118/2 and No.82, Panapakkam Village, Uthukottai Taluk, Tiruvallur District, dated 21.06.2011, which is valid upto 20.06.2016 and that condition No.3(ii) prescribed under Form-20B, makes the licencee responsible for being prosecuted, if the licencee cause any sale to a person, who has no valid requisite licence to sell or stock for selling or exhibit for sale or distributing the drug. Since the petitioner Company has supplied / sold drug to the first accused, who has no valid licence to sale or stock for selling or exhibit for sale, it is contended that the petitioner has committed offences under Sections 18(C) and 27(D) of the Act, r/w Rules 61 and 65 of the Rules.

11.After filing the counter affidavit in both cases, the petitioner in both cases have filed a better affidavit to the effect that the petitioner company has obtained a valid licence under Form-20B to sell stock or exhibit for sale or distribute the drug by wholesale at D.No.117, 118/1, 118/2 and No.82, Panapakkam Village, Uthukottai Taluk, Tiruvallur District, subject to certain conditions specified in Clause 3(ii), which is extracted hereunder:

> *"3(ii) No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug."*

12.From the above, it is evident that the Company had valid licence under Form-20B and that said licence is subject to the condition that the Company shall not indulge in selling drug to anyone, who does not hold a valid licence to sell, stock or exhibit for sale or distribute the drug. In this case, it is established that the first accused had no valid licence to sell, stock or exhibit for sale or distribute any drug in the premises from which the respondent seized the drugs. As per Rule 62 of the Drugs and Cosmetic Rules, 1945, separate licence has to be obtained in respect of every place of business, if drugs are sold or stocked or exhibited for sale at more than one place. Hence the contention of the learned Counsel for the petitioner in both cases that the dealer, namely, the first accused had valid licence to sell or stock the drug is not sustainable. Sections 18(C) and 27 of the Act, are extracted below for convenience:

> *"18(c) manufacture for sale 2[or for distribution], or sell, or stock or exhibit 2[or offer] for sale, or distribute any drug 4[or cosmetic],except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter."*

> *"27.Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter. --Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or*

offers for sale or distributes, —

(a) any drug deemed to be adulterated under section 17A or spurious under section 17B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not 2Ins. by Act 71 of 1986 3Amended. by Act 68 of 1982 (w.e.f. 01-02-1983) 31 of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;

(b) any drug—

(i) deemed to be adulterated under section 17A, but not being a drug referred to in clause (a), or

(ii) without a valid licence as required under clause (c) of section 18, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees;

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees;

(c) any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than five years and with fine which shall not be less than five thousand rupees;

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years but not less than one year;

(d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine;

Provided that the Court may, for any adequate and special

reasons, to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year."

13.Similarly, Rules 61 to 65 of the Drugs and Cosmetics Rules, 1945 are relevant in this context and hence they are extracted below:

"61. Forms of licences to sell drugs. (1) a licence 3[to sell, stock, exhibit or offer for sale or distribute] drugs other than those specified in Schedule C, C (1) and X and by retail on restricted licence or by wholesale, shall be issued in Form 20, Form 20-A or Form 20 -B, as the case may be;

Provided that a licence in Form 20-A shall be valid for only such drugs as are specified in the licence.

(2) A licence 3[to sell, stock, exhibit or offer for sale or distribute] drugs specified in Schedule C and C (1) excluding those specified in Schedule X, by retail on restricted licence or by wholesale shall be issued in Form 21, Form 21-A or Form 21-B, as the case may be.

Provided that a licence in Form 21-A shall not be granted for drugs specified in Schedule C and shall be valid for only such Schedule C (1) drugs as are specified in the licence.

(3)A licence to sell, stock, exhibit or offer for sale or distribute] drugs specified in Schedule X by retail or by wholesale shall be issued in Form 20-F or Form 20-G as the case may be.

62.Sale at more than one place. If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate licence shall be issued, in respect of each such place:

Provided that this shall not apply to itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority

62A. Restricted licences in Forms 20-A and 21-A. (a) Restricted licences in Forms 20-A and 21-A shall be issued subject to the discretion of the Licensing Authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.

(b)Licences to itinerant vendors shall be issued only in exceptional circumstances for bona fide travelling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available.

(c)The licensing authority may issue a licence in Form 21-A to a travelling agent of a firm but to no other

class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers, samples of biological and other special products specified in Schedule C:

Provided that travelling agents of licensed manufacturers, agents, of such manufacturers and importers of drugs shall be exempted from taking out licence for the free distribution of samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institution or research institutions.

62-B.Conditions to be satisfied before a licence in Form 20-A or Form 21-A is granted. --(1) A licence in Form 20-A or Form 21-A shall not be granted to any person, unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the licence applies:

Provided that this condition shall not apply in the case of licence granted itinerant vendors.

(2)In granting a licence under Rule 62-A the authority empowered to grant it shall have regard to :

(i) the number of licences granted in the locality during one year immediately preceding; and

(ii) the occupation, trade or business carried on by such applicant :

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these Rules or the previous cancellation or suspension of any licence granted thereunder, he is not a fit person to whom a licence should be granted under this Rule.

(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter make such order in relation thereto as it thinks fit.

62C. Application for licence to sell drugs by wholesale or to distribute the same from a motor vehicle:

(1)Application for the grant or renewal of a licence to sell by wholesale or to distribute from a motor vehicle shall be made to the Licensing Authority in Form 19-AA and shall be accompanied by 2[a fee of rupees five hundred]:

Provided that if the applicant applies for the renewal of a licence after its expiry but within six months of such expiry, the fee payable for renewal of such licence shall be rupees five hundred plus an additional fee at the rate of rupees two hundred and fifty per month or part thereof.

(2) A fee of rupees one hundred fifty shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

62D.Form of licences to sell drugs by wholesale or distribute drugs from a motor vehicles.

A licence shall be issued for sale by wholesale or for distribution from a motor vehicle of drugs other than those specified in Schedule and Schedule C(1) in Form 20BB and of drugs specified in Schedule C and Schedule C (1) in Form 21BB :

Provided that such a licence shall not be required in a case where a public carrier or a hired vehicle is used for transportation or distribution of drug.

63.Duration of licence. An original licence or a renewed licence to sell drugs, unless sooner suspended or cancelled, shall be valid for a period of five years on and from the date on which it is granted or renewed :

Provided that if the application for renewal of licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired if application for its renewal is not made within six months after its expiry.

63A.Certificate of renewal of a sale licence. The certificate of renewal of a sale licence in Forms 20, 20-A, 20-B,3[20-F, 20-G], 21, 21-A and 21-B shall be issued in Form 21-C.

63B. Certificate of renewal of licence.__ A certificate of renewal of a licence in Form 20BB or Form 21BB shall be issued in Form 21-CC.

64.Conditions to be satisfied before a licence in Form3[20, 20-B, 20-F,20-G 21 or 21-B] is granted .__(1)A licence in Form 3[20, 20-B, 20-F,20-G, 21 or 21-B] 6[to sell, stock, exhibit or offer for sale or distribute] drugs shall not be 7[granted or renewed] to any person unless the authority empowered to grant the licence is satisfied that the premise in respect of which the licence is to be 7[granted or renewed] are adequate,

equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies and are in charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs :

Provided that in the case of a pharmacy a licence in Form 20 or 21 shall not be granted or renewed unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with.

Provided further that licence in Form 20-F shall be 7[granted or renewed] only to a pharmacy and in areas where a pharmacy is not operating, such licence may be granted or renewed to a chemist and druggist.

Explanation. For the purpose of this rule the term 'Pharmacy' shall be held to mean to include every store or shop or other place : (1) where drugs are dispensed, that is, measured or weighed or mode up and supplied : or (2), where prescriptions are compounded; or (3) where drugs are prepared; or (4) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacy", "Pharmacist," "Dispensing Chemist" or "Pharmaceutical Chemist"; or (5) which, by sign, symbol or indication within or upon it gives the impression that the operations mentioned at (1), (2) and (3) are carried out in the premises; or (6) which is advertised in terms referred to in (4) above

(2)In granting a licence under sub-rule (1) the authority empowered to grant it shall have regard

(i)to the average number of licences granted during the period of 3 years immediately preceding, and

(ii)to the occupation, trade or business ordinarily carried on by such applicant during the period aforesaid :

Provided that the licensing authority may refuse to grant or renew a licence to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the Act or these Rules, or the previous cancellation or suspension of any licence granted thereunder, he is not a fit person to whom a licence should be granted under this rule. Every such order shall be communicated to the licensee as soon as possible.

Provided further that in respect of an application for the grant of a licence in form 20-B or form 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is

to be granted are:--

(i) of an area of not less than ten square meters; and

(ii) in the charge of a competent person, who—

(a) is a Registered Pharmacist, or,

(b) has passed the matriculation examination or its equivalent examination from a recognised Board with the four years experience in dealing with sale of drugs, or;

(c) holds a degree of a recognised University with one year's experience in dealing with drugs

Provided also that,--

(i) in respect of an application for the grant of a licence in Form 20 or Form 21 or both, the licensing authority shall satisfy itself that 5[the premises are of an area] of not less than 10 square meters, and

(ii) in respect of an application for the grant of a licence--

(A)In Form 20 or Form 21 or both, and

(B)In Form 20 B or Form 21B or both,

the licensing authority shall satisfy itself that the premises are of an area not less than 15 square meter;

Provided also that the provisions of the preceding proviso shall not apply to the premises for which licences have been issued by the licensing authority before the commencement of the Drugs and Cosmetic (1st Amendment) Rules, 1997]

(3) Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such an order in relation thereto as it thinks fit.

65. Condition of licences. Licences in 1[Form 20, 20-A, 20-B, 20-F, 20-C, 21, and 21-B] shall be subject to the conditions stated therein and to the following general conditions

(1) Any drug shall, if compounded or made on the licensee's premises be compounded or made under the direct and personal supervision of a registered Pharmacist

(2)The supply, otherwise than by way of wholesale dealing, 3[* *] of any drug supplied on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a registered Pharmacist.*

(3) (1) The supply of any drug 1[other than those specified in Schedule X] on a prescription of a

Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription. The following particulars shall be entered in the register: _

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the prescriber,

(d) the name and address of the patient, or the name and address of the owner of the animal if the drug supplied is for veterinary use.

(e) the name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof,

(f) in the case of a drug specified in 1[Schedule C or Schedule H] the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any,

(g) the signature of the 2[registered Pharmacist] by or under whose supervision the medicine was made up or supplied.

Provided that in the case of drugs which are not compounded in the premises and which are supplied from or in the original containers, the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose:

Provided further that if the medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion.

Provided further that it shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of:

(i) any drugs supplied against prescription under the Employees State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drug other than that specified in 1 [Schedule C or Schedule H] if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made and on condition that the provisions of sub rule (4)(3) of this rule are complied with.

(2) The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of the licence to sell by retail.

Provided that the Licensing Authority may require records to be maintained only in prescription register if it is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible.

(4) (1) The supply by retail, otherwise than on a prescription of a drug specified in Schedule C 3[* *] shall be recorded at the time of supply either :*

(i) in a register specially maintained for the purpose in which the following particulars shall be entered :

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the purchaser,

(d) the name of the drug and the quantity thereof,

(e) in the case of a drug specified in Schedule C, the name of the manufacturer, the batch number and the date of expiry of potency,

(f) the signature of the person under whose supervision the sale was effected, or

(ii) in a cash or credit memo book, serially numbered containing all the particulars specified in items (b) to (f) of sub clause (i) above.

NOTE: The entries in the carbon copy of the cash or credit memo which is retained by the licensee shall be maintained in a legible manner.

(2) The option to maintain a register or a cash or credit memo book shall be made in writing to the Licensing Authority at the time of application for the grant or renewal of a licence to sell by retail:

Provided that the Licensing Authority may require records to be maintained in a register if it is satisfied that the entries in the carbon copy of the cash/credit memo book are not legible.

(3)(i) The supply by retail of any drug shall be made against a cash/credit memo which shall contain the following particulars :

(a) Name, address and sale licence number of the dealer,

(b) Serial number of the cash/credit memo,

(c) the name and quantity of the drug supplied.

(ii) Carbon copies of cash/credit memos shall be maintained by the licensee as record.

(4)(i) Records of purchase of a drug intended for sale or sold by retail shall be maintained by the licensee and such records shall show the following particulars, namely:--

(a) the date of purchase,

(b)the name and address of the person from whom purchased and the number of the relevant licence held by him,

(c) the name of the drug, the quantity and the batch number, and

(d) the name of the manufacturer of the drug.

(ii) Purchase bills including cash or credit memo shall be serially numbered by the licensee and maintained by him in a chronological order,

(5)(1) Subject to the other provisions of these rules the supply of a drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his licence number under the Drugs and Cosmetics Act in which the following particulars shall be entered

(a) the date of sale.

(b) the name, address of the licensee to whom sold and his sale licence number. In case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a Registered Medical Practitioner for the purpose of supply to his patients the name and address of the authority, institution or the Registered Medical Practitioner as the case may be,

(c) the name of the drug, the quantity and the batch number,

(d) the name of the manufacturer.

(e) the signature of the competent person under whose supervision the sale was effected.

(2)Carbon copies of cash or credit memos specified in clause (1) shall be preserved as records for a period of three years from the date of the sale of the drug.

(3) (i) Records of purchase of a drug intended for resale or sold by wholesale shall be maintained by the licensee and such records shall show the following particulars, namely:--

(a) the date of purchase,

(b) the name, address and the number of the relevant licence held by the person from whom purchased,

(c) the name of the drug, the quantity and the batch number, and

(d) the name of the manufacturer of the drug.

(ii) Purchase bills including cash or credit memos

shall be serially numbered by the licensee and maintained by him in a chronological order.

(6) The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these Rules, and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(7) Except where otherwise provided in these Rules, all registers and records maintained under these Rules shall be preserved for a period of not less than two years from the date of the last entry therein.

(8)Notwithstanding anything contained in this Rule it shall not be necessary to record particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.

(9) (a) Substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner and in the case of substances specified in schedule X, the prescriptions shall be in duplicate,one copy of which shall be retained by the licensee for a period of two years.

(b)The supply of drugs specified in Schedule H or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years;

(10) For the purposes of clause (9) a prescription shall

(a) be in writing and be signed by the person giving it with his usual signature and be dated by him;

(b) specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is meant for veterinary use;

(c) indicate the total amount of the medicine to be supplied and the dose to be taken.

(11) The person dispensing a prescription containing a drug specified in Schedule H and Schedule X shall comply with the following requirements in addition to other requirements of these Rules

(a) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;

(b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions;

(c) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

11-A) No person dispensing a prescription containing substances specified in Schedule H or X, may supply any other preparation, whether containing the same substance or not, in lieu thereof.

(12) Substances specified in Schedule X kept in retail shop or premises used in connection therewith shall be stored

(a) under lock and key in cupboard or drawer reserved solely for the storage of these substances ;or

(b) in a part of the premises separated from the remainder of the premises and to which only responsible persons have access;

*(13) * * **

*(14) * * **

(15) (a) The description "Drugstore" shall be displayed by such licensees who do not require the services of a qualified person.

(b) The description "Chemists and Druggists" shall be displayed by such licensees who employ the services of a "3[registered Pharmacist]" but who do not maintain a "Pharmacy" for compounding against prescriptions:

(c) The description "Pharmacy", "Pharmacist", "Dispensing Chemist" or "Pharmaceutical Chemist" shall be displayed by such licensees who employ the services of a "registered Pharmacist" and maintain a "Pharmacy" for compounding against prescriptions:

Explanation:-- for the purpose of this rule,---

(i) "registered Pharmacist" means a person who is a registered Pharmacist as defined in clause (i) of Section (2) of the Pharmacy Act, 1948 (Act No. 8 of 1948).

Provided that the provisions of sub-clause

(i) shall not apply to those persons who are already approved as "qualified person" by the Licensing authority on or before 31st December 1969.

(ii) Date of Expiry of potency means the date that is recorded on the container, label or wrapper as the date up to which the substance may be expected to retain potency not less than or not to acquire toxicity greater

than that required or permitted by the prescribed test.

(16) The license shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

(17) No drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper;

Provided that any such drugs in respect of which the licensee has taken steps with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of potency pending such withdrawal, reimbursement or disposal, as the case may be, subject to the condition that the same shall be stored separately from the trade stocks 2and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words "Not for sale".

(18) No drug intended for distribution to the medical profession as free sample which bears a label on the container as specified in clause (viii) of sub-rule (1) of rule 96, and no drug meant for consumption by the Employees' State Insurance Corporation, the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government institutions, which bears a distinguishing mark or any inscription on the drug or on the label affixed to the container thereof indicating this purpose shall be sold or stocked by the licensee on his premises.

Provided that this sub- rule shall not be applicable to licensees who have been appointed as approved chemists, by the State Government in writing, under the employees' State Insurance Scheme, or have been appointed as authorized agent or distributor, by the manufacturer in writing, for drugs meant for consumption under the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government Institutions for drugs meant for consumption under those schemes 5[or have been appointed as authorized Depots or Carrying and Forwarding agent by the manufacturer in writing, for storing free samples meant for distribution to medical profession. subject to the conditions that the stock shall be stored separately from the trade stocks and shall maintain separate records of the stocks received and distributed by them.

19) The supply by retail of any drug in a container

other than the one in which the manufacturer has marketed the drug, shall be made only by dealers who employ the services of a "registered Pharmacist" and such supply shall be made under the direct supervision of the "registered Pharmacist" in an envelope or other suitable wrapper or container showing the following particulars on the label :

(a) name of the drug,

(b) the quantity supplied,

(c) the name and address of the dealer.

(20) The medicines for treatment of animals kept in a retail shop or premises shall be labelled with the words 'Not for human use for treatment of animals only' and shall be stored

(a) in a cupboard or drawer reserved solely for the storage of veterinary drugs, or

(b) in a part of the premises separated from the remainder of the premises to which customers are not permitted to have access.

(21) (a) The supply of drugs specified in Schedule X shall be recorded at the time of supply in a register (bound and serially page numbered) specially maintained for the purpose and separate pages shall be allotted for each drug.

(b) The following particulars shall be entered in the said register, namely:--

(i) Date of transaction;

(ii) Quantity received, if any, the name and address of the supplier and the number of the relevant licence held by the supplier;

(iii) Name of the drug;

(iv) Quantity supplied;

(v) Manufacturer's name;

(vi) Batch No. or Lot No;

(vii) Name and address of the patient purchaser;

(viii) Reference Number of the prescription against which supplies were made.

(ix) Bill No and date in respect of purchases and supplies made by him;

(x) Signature of the person under whose supervision the drugs have been supplied."

14.From the plain reading of the Section 18, no person can manufacture for sale or distribute or sale or exhibit for sale or distribute any drug except in accordance with the conditions of, a licence issued for such purpose under this chapter. A manufacturer also has to sell or distribute the drugs and hence, a licence under Form-20B was also obtained by the petitioner company. As referred to above, one of the conditions specified under Form-20B is that the drug shall not be sold to a person, not holding the requisite licence to sell, stock or exhibit for sale or distribute

the drug.

15.Section 27(d) of the Act also stipulates that any person who sell or stock or exhibit or distribute any drug in-contravention of any other provisions of the Act or Rule made thereunder is punishable. As per Rule 61, a licence to sell or stock or exhibit or offering for sale or distribute the stock, shall be issued under Forms-20, 20-A and 20-B, as the case may be. Rule 62 stipulates that, if drugs are sold or stocked for sale at more than one place, separate application is required in respect of each such place. Rule 65 however, mandates that the licence under Form 20-B, is subject to the conditions stated under Rule 65. As pointed out earlier, one of the conditions found in Form 20-B, is that the licencee shall not sale or distribute the drugs to a person, who has no valid licence to sell or stock. Hence, this Court is of the view that prima facie case is made out as against the petitioner company.

16.The next submission for the learned Counsel for the petitioner in both cases is that the fifth accused, who is the Managing Director of the Company cannot be prosecuted. The learned Counsel for the petitioner in both cases submitted that the complaint does not disclose any specific reason to implicate the former Managing Director and that the Managing Director cannot be prosecuted unless he is made liable in accordance with Rules. The learned Counsel for the petitioner in both cases relied upon by the judgment of the Honourable Supreme Court, in the case of State of Haryana vs Brij Lal Mittal and others reported in (1998) 5 SCC 343, wherein, the Honourable Supreme Court has held as follows:

> *"...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 baid 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."*

17.Again, the learned Counsel for the petitioner in both cases relied upon a judgment of the Karnataka Highcourt, in the case of Sanjay G.Ravankar vs. State by Drug Inspector, Uttar Kannada District, Karwar, reported in ILR 2002 KAR 475, wherein, it has

been held as follows:

"15. Taking into consideration the Director, Manager, Secretary or other officers of a company are made vicariously liable to the collective action of a company, who itself would be an accused in the offences like one on hand, there are certain restrictions and preventive measures placed by the legislation itself for making them co-accused along with the company. Prima facie requirement is that the complainant to substantiate the basic requirements like the present accused is, to show he is in charge of, or responsible for the conduct of the business of the company, be it in any capacity and if he is the Director, Manager, Secretary or officer of the company it should be averred and shown that the offence took place with his consent or connivance or is also attributable to the neglect on the part of such person (Director, Manager, Secretary and other officer). Keeping in view the observations of the Apex Court in the case of Sham Sundar and Ors. v. State of Haryana, which are to the following effect.--

> *"More often it is common that some of the partners of a firm may not even be knowing of what is going on day-to-day in the firm. There may be partners, better known as sleeping partners who are not required to take part in the business of the firm. There may be ladies and minors who were admitted for the benefit of partnership. They may not know anything about the business of the firm. It would be a travesty of justice to prosecute all partners and ask them to prove under the proviso to Sub-section (1) that the offence was committed without their knowledge. It is significant to note that the obligation for the accused to prove under the proviso that the offence took place without his knowledge or that he exercised all due diligence to prevent such offence arises only when the prosecution establishes that the requisite condition mentioned in Sub-section (1) is established".*

(emphasis supplied) It is to be noted that unlike the first information as required under Section 154 of the Criminal Procedure Code which need not be elaborate and contain all the history of the case, this complaint under Section 200 of the Criminal Procedure Code filed for specific and substantial offences under the independent acts like Drugs and Cosmetics Act. In the present case it is the public servant on his own investigation in respect of commission of offences under the Act lodges a complaint under Section 200 of the Criminal Procedure

Code. In such an event the accused person who is to be vicariously liable and this aspect he may come to know only after taking of cognizance and issuance of process against him and only when he can either state that he does not fall either under Sub-section (1) of Section 34 of the Act viz., that he is not a person in charge of, and was responsible to the assets of the company or the alternate arguments that even though he is the Director, Manager, Secretary or other officer of the company, it is not shown that the offence was committed with his consent or connivance or is attributable to any neglect on his part. As observed by the Apex Court in the case of Girdhari Lal Gupta v. D.N. Mehta, followed in the subsequent pronouncements in the case of Sham Sundar, supra, merely because a person is a Director may not be concerned with day-to-day working of the company and as such only because of his holding of position, he cannot be straightaway arrayed as accused unless prima facie there is averment to clearly indicate what exactly is the role played by such Director, which resulted in the commission of the offence.

16. In the present case petitioners (accused 4 to 6 and 8) are the Directors of the company. There is no specific averment about the role of each of Directors except baldly stating in the complaint that these are the Directors of accused 1-company and hence they are to be held responsible for the day-to-day affairs of the firm or company. In my view, this would not be a sufficient averment. From the words used in the complaint, for example at para 7 that accused 4 to 6 are working partners of the firm and are held responsible for the day-to-day affairs indicate that the complainant wants to infer the fact that merely because such person is a director, he is deemed to be responsible for the commission of the offence. As observed by the Apex Court in the aforesaid decisions, there are number of different types of partners in a firm or a company. He may be working partner, sleeping partner or partners who are minors. Merely because he is a partner, it cannot be straightaway inferred that he is responsible for the day-to-day working or he is in charge of and responsible for the very operation of the company and more so towards the commission of the crime in question. No doubt the proviso to Section 34(1) leaves it open to such co-accused to prove before the Trial Court such offence was committed without his knowledge or in spite of his exercising due diligence in proving the commission of such offence but that is at the trial stage. As observed by the Apex Court in the case of M/s. Pepsi Foods Limited v Special Judicial Magistrate, if there is absence of such prima

facie allegation or averment why the person should be asked to undergo the agony of a criminal trial and make him to prove the fact which was not even averred basically by the complainant in his complaint filed under Section 200 of the Criminal Procedure Code. Hence, in my view, that apart from saying that the co-accused is holding certain posts like Director, Manager or Secretary or any other officer of the company, the main accused, it must be clearly averred in the complaint itself as to whether he was in charge of the company or its affairs and how he was concerned with the commission of the offence itself. Taking into consideration the various pronouncements of the Apex Court in this regard in respect of similar provisions arising under the different special enactments creating various liabilities on the partners of a firm or Directors of a company, I hold that the complainant in his complaint should mention and aver the details as to how the particular vicariously liable person or accused is concerned with the commission of the crime itself and unless and until the same is done, merely because he is a Director or an officer cannot be held to be straightaway as an accused.

17. It is to be noted that the complaint is by a public servant (State Machinery). Unlike private complaint who will not have sufficient resources at hand to investigate or find out as to the exact role of each of the co-accused, in my view, it is necessary to aver the actual role played by each of the co-accused so as to make them vicariously liable for the commission of the offences by the main accused, the company or the firm.

18. In the present case as noted except vague and bald averments in paragraphs 7 to 9 and paragraph 44 insofar as accused 4 to 6 and 8 are concerned, I do not find any necessary basic averments except stating that they are the Directors and hence are deemed to be guilty, There are absolutely no material averments to hold with guilt of each of the accused on prima facie material. As these are the specific offences making liability of persons concerned with a company (the main accused) principally in criminal case, the learned Magistrate at the time of taking of cognizance itself is required to apply his mind in this regard as it is open for him not to take cognizance at the initial stage itself or taking cognizance of only such persons against whom there is prima facie material. In the present case except a bare and bald statement of the complaint insofar as accused 4 to 6 and 8 are concerned that it is deemed that they are liable to be arrayed as accused merely because they are Directors of the company, is not a prima facie indication of their committing the offence vicariously. In my view,

there is no sufficient application of mind on the part of the learned Magistrate in this regard. This action of taking cognizance and issuing process insofar as accused 4 to 6 and 8 are concerned, in my view, is without application of mind in the absence of availability of or making out prima facie case is concerned and hence liable to be set aside or quashed."

18.In the licence that was issued to the petitioner company under Form-20B, one Mr.N.Ravikumar, P.G.D.B.A., is shown as the qualified person incharge. It was therefore, submitted that the respondent could proceed only against the said person, who is incharge of the Distribution at the place, in which the petitioner company is stocking the drugs for sale and for distribution. All along, it was the contention of the learned Counsel for the petitioner in both cases that Form 20B and Rules 61 to 65 of Drugs and Cosmetics Rules, 1945, are not applicable to the petitioner company, who is the manufacturer of drugs. Only in the counter affidavit, it was pointed out that the petitioner company had obtained a licence under Form 20B. It is admitted that the fifth accused was a person, who was then the Managing Director, when the inspection was conducted and samples were taken. It is admitted that the dealer to whom, the drugs were supplied, did not have a valid licence either to stock or to sell or distribute the drug. Hence Section 18(c) of the Act and Rule 27 (d) of the Rules are applicable to the petitioner company.

19.The question who is responsible to effect the sale and whether the fifth accused is authorised to appoint the dealer or to take a decision with regard to the supply of drug to the first accused is a question to be decided on the basis of evidence. This Court cannot decide at this stage on the basis of materials that the petitioner in both cases are not involved in any offence. Since Criminal Original Petitions were filed only on the ground that the licence under Form-20B is not applicable to a manufacturer and the petitioner company has consciously suppressed the fact that the said licence was obtained by the petitioner, this Court is of the view that it is a case, where the facts can be finally ascertained after the trial on the basis of evidence. The complaint cannot be quashed without any further investigation in this case, especially this Court has found that the petitioner has made an attempt to suppress the licence that was obtained under Form-20B. It was further contended that the petitioner cannot be made liable for the irregularity committed by the dealer and that the mistake was also rectified later. It is contended further that the first accused has valid licence now and that the mistake of the dealer can be ignored. In this regard, it is relevant to refer the judgment of the Honourable Supreme Court in the case of Swantraj and others vs. State of Mahrastra reported in AIR 1974 SCC 517.

20.In the case before the Honourable Supreme Court, a peculiar circumstance arose. The petitioner before the Honourable Supreme Court had a valid wholesale dealer's licence to stock drugs at Bombay and had a further licence to distribute the drugs through a motorvan throughout the territory of Maharastra. However, the petitioner booked certain drugs for which they had licence to distribute by lorry to a place called Yeotmal. It was further contended before Honourable Supreme Court that the motorvan of the petitioner was expected to reach the place "Yeotmal" by about the time when the goods were due to arrive and that the petitioner would collect the drugs so booked from the lorry and distribute them as per the instruction given by the Firm. Unfortunately, the motorvan was delayed by three days and one of the partners of the partnership firm released the goods from the transport operator and temporarily kept them in the godown of a local drug dealer. The question before the Honourable Supreme Court was whether the act of appellant in temporarily storing drugs, not for immediate sale, but to intend for ultimate sale in other parts of the State, contrary to Sections 18(c) and 27(b) of the Act?

21.The Honourable Supreme Court even though found that there was no intentional act on the part of the petitioner / dealer, has held in paragraph 10 of the judgment as follows:

> *"If any godown, depot or premises become the nidus of spurious. time-expired or unscientifically stored drugs, can they be allowed to escape the coils of the penal law on the plea that they are not to be sold there, without great peril to patients? Then legal shelter for spurious drug rackets would be judicially ensured. And this colours construction. Stocked for sale there and then? or to be sold certainly but elsewhere later ? are the two alternatives flowing from the language of Sec. 18 (1) (c). The former permits abuse through, loopholes, the latter tightens up but loads the dealer with expenses and need for more licences. Since risk to life and health is avoided by the latter interpretation, we hold that the storage, even though for short spells and on ad hoc basis and without intent to sell at that place but as part of the sales business, comes within the scope of storage for sale' in Sec. 1.8(c) and R. 62. To loosen the law in its joints is to play with life and therefore anti-humanist."*

22.The object of the enactment is very clear and that every dealer is required to get licence for stocking. The drug can also be stored before selling only if the premises has got required infrastructure. However, manufacturer also has to sell or dispose of the drugs. No manufacturer can sell the goods to any unlicensed dealer. In that context, the allegations found in the complaint attract Sections 18(c) and 27(d) r/w Rules 61 and 65 and

conditions of licence under Form-20-B. It is open to the petitioner in Crl.O.P(MD)No.11883 of 2017 to prove by evidence that he cannot be prosecuted for the offences and that the person incharge for appointing a dealer is somebody else. In such case, it is open to the respondent to proceed against the person, who can be held liable for prosecution.

23. As a result, these Criminal Original Petitions are dismissed. This is not a case, where the petitioner can be discharged at this stage without further evidence. Consequently, connected miscellaneous petitions are closed.

Sd/-
Assistant Registrar(AS)

/True Copy/

Sub Assistant Registrar

To

1. The Judicial Magistrate Court No.I,
   Trichy.

2. The Drugs Inspector,
   Trichy II Range,
   Trichy Zone, Trichy – 620 018.

3. The Additional Public Prosecutor,
   Madurai Bench of Madras High Court,
   Madurai.

+1cc to Mr.S.Sukumar, Advocate Sr.No.67096
Cmr
MK/SV MMS/SAR 1/18.06.2018/26P/5C

order made in
CRL.OP.(MD).Nos.10853 and 11883 of 2017
06.06.2018