IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 08.09.2025

CORAM :

THE HONOURABLE MR. JUSTICE N. SATHISH KUMAR

Crl.O.P.Nos.22858, 25516, 25808, 25855 of 2023,
24167 & 24492 of 2025
and
Crl.M.P.Nos.16006, 17941, 16008, 17904, 17903,
17699, 17700, 17942 of 2023,
16506, 16508, 16739 & 16740 of 2025

M/s.Hetero Drug Ltd.,
Represented by its Authorised Signatory,
P.Yogendra Reddy
22-110, IDA Jeedimelta
Hyderabad – 55. ... Petitioner
in Crl.O.P.No.22858 of 2023

J.Sambi Reddy ... Petitioner
in Crl.O.P.No.25516 of 2023

G.Palleswara Rao ... Petitioner
in Crl.O.P.No.25808 of 2023

Dr.B.Parthasaradhi Reddy ... Petitioner
in Crl.O.P.No.25855 of 2023

Mita Golecha ... Petitioner
in Crl.O.P.No.24167 of 2025

J.Bharathi Kumar ... Petitioner
in Crl.O.P.No.24492 of 2025

Vs.

State represented by
S.R.Arumugam
Drug Inspector
Salem 1 Range i/c.
No.7, Thiruvalluvar Street,
Subramania Nagar,
Salem – 5. ... Respondent
in all petitions

Prayer in Crl.O.P.Nos.25516, 22858, 25808, 25855 of 2023 : Criminal Original Petition filed under Section 428 of the Code of Criminal Procedure to call for the records connected with C.C.No.247 of 2010 on the file of the Judicial Magistrate Court No.2, Salem, and quash the same.

Prayer in Crl.O.P.Nos.24167 & 24492 of 2025 : Criminal Original Petition filed under Section 428 of the Code of Criminal Procedure to call for the records connected with C.C.No.247 of 2010 on the file of the Judicial Magistrate Court No.2, Salem, and quash the same as against the petitioner.

For Petitioner : Mr.B.Kumar
Senior Counsel
for Mr.S.Ramachandran
in Crl.O.P.Nos.25516, 22858,
25808, 25855 of 2023

: Ms.M.Sheela
and Mr.H.Siddharth

For Respondent : Mr.K.M.D.Muhilan
Additional Public Prosecutor
in all petitions

COMMON ORDER

These Criminal Original Petitions are filed to quash the private complaint filed by the Drugs Inspector, Salem I Range, against the petitioners for violation under Section 18(a)(i) of the Drugs and Cosmetics Act, 1940, r/w. Section 17(b) Rule 96(1) of the Drugs Rules, 1945 and Section 18(c) of the Drugs and Cosmetics Act r/w. Rules 65(5)(1) and 65(5)(3) of the Drugs Rules, punishable under Section 17(d) of the Drugs and Cosmetics Act.

2.The crux of the complaint is as follows :

2.1.On 20.12.2004, the Drugs Inspector, inspected the premises of M/s.Venkatavinayaga Distributors, situated at No.3/33, Chinneri Vayalkadu, Pallapatty, Salem – 9 and found that the following drugs were stocked for sale :

Enthusia 50 mg – B.No.01014H - 777x4s

Enthusia 50 mg – B.No.03063H - 50x4s

The said drugs were packed as 10 x 4s and in the sales bills also, it was mentioned as packing 10 x 4s. In the outer carton's label, there were the following :

1.The Name of the Drug
2.Batch No.
3.Quantity of the Tablets
4.Manufacturing Date
5.Expiry Date
6.Maximum Retail Price

Whereas, the label of the outer carton of the packing did not bear the following :

1.The active ingredients and formula
2.Manufacturer's name and address
3.Statutory warning, etc.,

2.2.Thus, it is the case of the complainant that “Enthusia 50” tablets do not comply with the labelling provisions of the Drugs and Cosmetics Act, 1940 as required under Rule 96 of Drugs Rules, 1945, and thus, the

said drug falls under “Misbranded drugs” as per Section 17(b) of the Drugs and Cosmetics Act, 1940. Hence, the respondent filed the present complaint before the Judicial Magistrate Court No.2, Salem.

2.3.The said complaint was taken on file in C.C.No.247 of 2010 by the learned Judicial Magistrate. Challenging the same, the present Criminal Original Petitions are filed by A1 to A4, who are the manufacturers of the drugs; and A8 and A9 who are the distributors of the drugs.

3.The complaint is sought to be quashed mainly on the ground that the drug is sold only on medical prescription of qualified Doctors and only one or two tablets will be purchased by a person. Therefore, to be convenient, the tablets are put in a carton. Each carton contains 10 tablets. Each of the carton contains all the details duly printed on it like date of manufacture, period of expiry, manufacturer's name, etc. When the carton boxes are delivered to the retailer for sale, 10 such carton boxes, each containing 10 tablets, will be put in a larger carton. This larger carton box, however, does not contain any details. However, it is the contention of the petitioners that the same will not amount to misbranding within the

meaning of the Act. The complaint is totally overlooked that it is not necessary to print on the wrapper, case or other covering used solely for the purpose of packing, transport or delivery as per Rule 96(3)(ii) of the Drugs Rules, 1945. Therefore, the very complaint is liable to be quashed.

4.Whereas, in the counter affidavit filed by the complainant, it is stated that, on inspection at the premises of M/s.Venkatavinayaga Distributors, it was found that they have stocked Enthusia 50 mg tablets. Though the outer carton's label contained the name of the drug, batch number, quantity, manufacturing date, expiry date, maximum retail price, the outer carton did not contain the active ingredients and formula, manufacturer's name and address, statutory warning, etc. Therefore, the said drug “Enthusia 50” does not comply with the labelling provisions of the Drugs and Cosmetics Rules 1940 as required under Rule 96 of Drugs Rules, 1945 and therefore, the same falls under “Misbranded Drugs” as per Section 17(b) of the Drugs and Cosmetics Act, 1940.

5.It is further stated in the counter affidavit that the drugs were seized and samples were sent for analysis and it was reported as standard quality.

Thereafter, it was enquired and found that the drugs were manufactured by M/s.Hetero Drugs Ltd., IDA., Jeedimetla Hyderabad. The drugs were supplied by M/s.Bhagwan Pharmaceuticals, 265, I Floor, Sydenhams Road, Choolai, Chennai – 600 112. It was further found that the said M/s.Bhagwan Pharmaceuticals, in turn, acquired the drugs from M/s.Moti Pharmaceuticals, Chennai, who, in turn, acquired them from M/s.Lupin Limited and M/s.Lupin Limited purchased the drugs from the manufacturer M/s.Hetero Drugs Ltd.

6.A show cause memo was issued to the manufacturer M/s.Hetero Drugs Ltd. M/s.Hetero Drugs Ltd. replied that the foil and inner cartons (saleable carton) contain all the relevant information like label claim and colours used, drug licence no., warning manufacturer's address, marketers address, Batch No., Manufacturing Date as per Drugs and Cosmetics Act. It was stated that the outer carton is used only to hold 10 inner cartons for the convenience in distribution and accounting purpose.

7.However, it is the contention of the complainant that, as per Rule 96(3)(i) of the Drugs Rules, all the particulars prescribed under Sub-Rule

(1) of Rule 96 shall be printed or written in indelible ink either on the label borne by a container or on a label or wrapper affixed to any package in which the container is issued for sale. Therefore, when such particulars are not available on the outer carton, the drugs will fall under "misbranded drugs". When the manufacturer has admitted that the outer carton is used to hold 10 inner cartons for the convenience in distribution and accounting purpose, it implies that the outer packing is a carton and not a wrapper, which can be rightly interpreted as for "sale purpose". Therefore, when the large carton does not contain all the particulars as required under the Rules, it has to be construed that the labelling provisions have been contravened.

8.Learned Senior Counsel appearing for the petitioners would submit that the labelling is required only for the sale of the drugs. As per Rule 96(1) of Drugs Rules, 1945, all the particulars stipulated therein have to be printed or written in indelible ink and should appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed. However, the said Rule is subject to other provisions of the Rules. Rule 96(3)(ii) of Drugs Rules makes it clear that, nothing in the Rules shall be deemed to require the

labelling of any transparent cover or of any wrapper, case of other covering used solely for the purpose of packing, transport or delivery. Therefore, it is his contention that the very initiation of prosecution itself is not proper.

9.Further, it is the contention of the learned Senior Counsel that in Enthusia-50 tablets 10x4s, all the particulars as required under law have been printed on the strips. Whereas, only for the purpose of transport to the distributors, the 10 x 1 x 4s tablets have been packed in one package. Therefore, merely on the basis of the inspection made at the distributor end, it cannot be said that there was violation of Rule 96(1) of the Drugs Rules. The very complaint itself indicates that the inspection was made only at distributor's place. It is not the case of the complainant that, while selling the tablets, the tablets have been sold without any particulars as mandated under Rule 96 of Drugs Rules. It is his contention that only for the end users, such particulars are required. Therefore, at no stretch of imagination, it amounts to misbranding. Hence, the learned Senior Counsel seeks to quash the entire complaint.

10.Whereas, the learned Additional Public Prosecutor appearing for

the respondent/complainant would submit that Rule 96(1) makes it clear that all the particulars stipulated therein have to be printed in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed. However, since the larger carton did not contain such particulars, it attracts the offence. Even for distribution, if the drug is not labelled as per the provisions of Rule 96(1), it amounts to misbranding. Hence, the complaint cannot be quashed at this stage.

11.Heard the learned counsel on either side and perused the materials available on record.

12.The prosecution is initiated on the premise that there is misbranding of the drug “Enthusia 50”, since all the particulars as mandated under Rule 96 of the Drugs Rules were not printed on the outer carton containing the tablets.

13.It is relevant to note that Section 17 of the Drugs and Cosmetics Act, 1940, deals with “misbranded drugs”. Section 18 of the Act deals with

"Prohibition of manufacture and sale of certain drugs and cosmetics". Section 19 of the Act deals with "plea of the accused", which provides that it shall be no defence in a prosecution under Chapter-IV that the accused was ignorant of the nature or substance of quality of the drug or cosmetic in respect of which the offence has been committed. However, Sub-Clause (3) of Section 19 reads as follows :

> ***"19.Pleas : …. (3)*** *A person, not being a manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of Section 18 if he proves-*
>
> *(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;*
>
> *(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and*
>
> *(c) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as and when he acquired it."*

Though ignorance cannot be a defence under Chapter-IV, Sub-Clause (3) of Section 19 makes it clear that, if the distributor is able to show that he is only a distributor and he is not the manufacturer of the drugs, he is not liable, if he acquired the drug or cosmetic from a duly licenced

manufacturer or dealer thereof.

14.From the complaint itself, it is not the case of the prosecution that the manufacturer did not have any licence for manufacture of drugs. The only charge against the petitioners is that the said drug Enthusia 50 has not been labelled properly as required under Rule 96(1) of the Drugs Rules.

15.Rule 96 of the Drugs Rules, 1945, reads as follows :

"96.Manner of Labelling —

(1) *Subject to the other provisions of these Rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely :—*

(i) *the name of the drug*

(A) for this purpose, the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be—

(a) for drugs included in the Schedule F

or Schedule F (1), the name given therein;

(b) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'I.P.', or, as the case may be, by the recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards;

(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';

(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance;

(AA) Notwithstanding anything contained in these rules, the additional requirements of labeling specified vide notification number GSR 222(E), dated the 13th March, 2018 published in the Gazette of India, Extraordinary, Part-II – Section (3) – Sub-section (I) shall be on voluntary basis for a period beginning on the 13th September, 2018 and ending on the 31st March, 2019 and thereafter shall be mandatory.

(ii)*A correct statement of the net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system.*

(iii) *The content of active ingredients :*

This shall be expressed -

(a) for oral liquid preparations in terms of the content per single dose, being indicated in 5 millilitres.

Provided that where the dose is below 5 millilitres the contents of active ingredients may be expressed in terms of 1 millilitre or fraction thereof:

Provided further that where the single dose is more than 5 millilitres, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the licensing authority;

(b) for liquid parenteral preparations ready for administration in terms of 1 millilitre or percentage by volume or per dose in the case of single dose container :

Provided that if the preparation is contained in an ampoule it will be enough if the composition is shown on the label or wrapper affixed to any package in which such ampoule is issued for sale;

(c) for drugs in solid form intended for parenteral administration, in terms of units or weight per milligram or gram;

(d) for tablets, capsules, pills and the like,

in terms of the content in each tablet, capsule, pill or other unit, as the case may be;

(e) for other preparations, in terms of percentage by weight or volume or in terms of unitage per gram or millilitre, as the case may be: Provided that clause (iii) shall not apply to the pharmacopoeial preparations where the composition of such preparation is specified in the respective pharmacopoeia and to a preparation included in the National Formulary of India.

(iv) *The name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured:*

Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer and his principal place of 5 [manufacture] is shown.

(v) *A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words 'Batch No.' or 'B. No.' or 'Batch' or 'Lot No.' or 'Lot'.*

(vi) *Every drug manufactured in India shall bear on its*

label the number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufcaturing Licence Number' or 'Mfg. Lic. No.' or 'M.L.'.

(vii) *Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture, and the date of expiry of potency, and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule under the conditions of storage specified therein. Drugs and their preparations not included in Schedule P, shall bear on their labels the date of their manufacture and also the date of their expiry which shall not exceed sixty months from the date of manufacture:*

Provided that this period may be extended by the Licensing Authority specified in clause (b) of Rule 21 in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension.

(viii) *Drugs specified in Schedule C(1) and their*

preparations including combinations in other drugs shall bear on their labels (a) the date of manufacture, and (b) date of expiry of potency fixed by the manufacturer:

Provided that drugs in bulk form included in Schedule C(I) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency:

Provided further that no reference shall be made to any other licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed therewith.

***(ix)** Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words 'Physician's Sample-Not to be sold' which shall be overprinted.*

***(x)**If any preparation contains not less than 3 per cent by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.*

(xi)*In addition to the other particulars which are required to be printed or written under these Rules, the label of innermost container of the following categories of drugs and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than 1mm in width and without disturbing the other conditions printed on the label under these rules, namely: —*

Narcotic analgestics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules 'G', 'H', and 'X' whether covered or not in the above list:

Provided that the provisions of this clause shall not apply to:

(a) preparations intended for animal treatment;

(b) preparations intended for external use;

(c) ophthalmic preparations and ear drops; and

(d) sterile preparations such as sutures, surgical dressings and preparations intended for parenteral use.

(xii) *Drugs and their preparations including combinations with other drugs imported into the country*

shall also bear on the label, the license number under which the drug is imported, preceded by the words 'Import License' and the name and address of the importer.

(xiii) *The name of the marketer of the drug and its address, in case the drug is marketed by a marketer :*
*Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown.***"**

A perusal of the above makes it clear that, subject to other provisions of the Rules, the labelling is absolutely to be done.

16.Rule 96(2) of the Drugs Rules reads as follows :

"96. … (2) (i) *The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.*

(ii) *The following particulars, in addition to those specified under sub-rule (1) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the*

container of a contraceptive, other than a mechanical contraceptive, is packed, namely : -

(a) the date of manufacture;

(b) the date upto which the contraceptive is expected to retain its properties;

(c) the storage conditions necessary for preserving the properties of the contraceptive upto the date indicated in sub-clause (b) :

Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.”

17.Rule 96(3) of the Drugs Rules, reads as follows :

“96. … (3) (i) *The particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.*

(ii) *Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.”*

18.Sub-Clause (ii) of Clause (3) of Rule 96 makes it clear that nothing in the Rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

19.Admittedly, each strip containing four tablets (1 x 4s) contained all the particulars. Only the outer carton containing 10 such strips did not contain all the particulars as required under Rule 96(1) of the Drugs Rules. It is relevant to note that the inspection has been conducted only at the distributor's place. The very object of the Act is that the tablets which are sold to the end users at the seller's end should contain all the particulars. Admittedly, each strip which contains four tablets (1 x 4s) has been labelled properly. Therefore, merely because the labelling of the outer larger container containing 10 such tablets, received as such by the distributor from the manufacturer, did not contain all the particulars, it cannot be said that there was violation of Rule 96(1), when Rule 96(3)(ii) makes it clear that labelling is not required on any transparent cover or any wrapper or case or other covering used solely for the purpose of packing, transport or delivery. When each strip of medicine, which is saleable, has been properly

labelled, merely because the outer carton which is used to pack 10 such strips for the convenience of transport and accounting did not contain all the particulars as required under Rule 96(1), it cannot be said that the same amounts to misbranding.

20.It is pertinent to note that Rule 96(1), which mandates labelling, opens with a phrase *"subject to the other provisions of these Rules"*. Whereas, the other provision Rule 96(3)(ii) specifically makes it clear that such labelling is not required on any transparent cover or any wrapper or case or other covering used solely for the purpose of packing, transport or delivery. Therefore, Rule 96(1) will operate only in the absence of any other provision which mandates labelling even on the cover used for packing, transport or delivery. Therefore, when Rule 96(3)(ii) does not mandate such labelling on the cover used for transporting, this Court is of the view that it cannot be said that there is a violation of Rule 96(1).

21.Admittedly, since the saleable carton contains all the relevant information like label claim, colours used, drug licence no., warning, manufacturer's address, marketer's address, Batch No., Manufacturing Date,

expiry date, etc., as per the Drugs Rules, and the outer carton is used only to hold the inner cartons for the convenient packing, transport and accounting purposes, this Court is of the view that the same cannot be construed to mean that there was a violation of Rule 96(1) of the Drugs Rules. As there is no serious violation and it is not the case of the complainant that the violation was found at the seller's end while selling the tablets, the prosecution case, even taken in entirety as such, does not attract any offence. In such view of the matter, I do not find any substance in the complaint. Therefore, this Court is of the view that the prosecution will not succeed in establishing the guilt of the petitioners. Therefore, keeping this complaint pending any further will serve no purpose. It is also relevant to note that the inspection was carried out in the year 2005 and the prosecution has been launched in the year 2007 and the complaint has been taken on file in 2010 and the same is pending all these years. That itself is a harassment. Therefore, pendency of this complaint for all these years has also violated the concept of speedy trial guaranteed under Article 21 of the Constitution of India.

22.Further, in the meanwhile the complaint was taken on file in 2010,

an amendment has been brought to the Act in the year 2008, wherein, the State Drug Control Organisations were placed under obligation to constitute Screening Committees. The following guidelines have been issued :

> ***"(d)*** *In particular the Guidelines mandate that The State Drug Control Departments shall constitute screening committees comprising of at least three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are proposed to be launched. The committee may submit written opinion on the investigation reports regarding their feasibility of taking legal action. The criminal intent or gross negligence should be taken into consideration while recommending actions like prosecution etc. Care should be taken that charges framed are not based on inappropriate provisions which may be difficult to prove in the court of law in the absence of proper justification or evidence. Cases of failing in assay, brand name disputes and non-renewal of manufacturing licence in time should be examined on their merits before recommending prosecution in such cases and further that Prosecutions by the Inspectors shall be launched on the basis of written permissions of the controlling authority and this authority in turn shall consider the recommendations of the screening committee while taking final decision in the matter."*

Such being the position, the matter has not been placed even before the Screening Committee. Such a procedure also has not been followed.

23.It is brought to the notice of this Court that the complaint as against A5 and A6, who are the marketing agents of the drug "Enthusia – 50", has already been quashed by this Court by order dated 25.04.2017 in Crl.O.P.No.15641 of 2011 on the ground that they are not the manufacturers but only the marketing agents of the drugs.

24.Since this Court has held that there is no substance in the complaint and that the prosecution will not succeed in establishing the guilt of the accused, this Court is inclined to quash the entire complaint.

25.Accordingly, these Criminal Original Petitions are allowed and the entire complaint in C.C.No.247 of 2010 on the file of the Judicial Magistrate Court No.2, Salem, is quashed. Consequently, connected miscellaneous petitions are closed.

08.09.2025

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Internet : Yes
Index : Yes / No
Speaking order : Yes / No
Neutral Citation : Yes / No

To

1.The Judicial Magistrate Court No.2,
Salem.

2.The Drugs Inspector,
Salem 1 Range i/c.
No.7, Thiruvalluvar Street,
Subramania Nagar,
Salem – 5.

3.The Public Prosecutor,
High Court, Madras.

N. SATHISH KUMAR, J.

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Crl.O.P.Nos.22858, 25516, 25808,

08.09.2025