2026:AHC:9173

HIGH COURT OF JUDICATURE AT ALLAHABAD

CRIMINAL REVISION No. - 4884 of 2024

M/S Marion Biotech Pvt Ltd and 5 others

…..Revisionist(s)

Versus

Union of India and another

…..Opposite Party(s)

With

CRIMINAL REVISION No.-5442 of 2025

M/S Marion Biotech Pvt Ltd and 5 others

…..Revisionist(s)

Versus

Union of India and another

…..Opposite Party(s)

With

CRIMINAL REVISION No.-5443 of 2025

M/S Marion Biotech Pvt Ltd and 5 others

…..Revisionist(s)

Versus

Union of India and another

…..Opposite Party(s)

With

CRIMINAL REVISION No.-5444 of 2025

M/S Marion Biotech Pvt Ltd and 5 others

…..Revisionist(s)

Versus

Union of India and another

…..Opposite Party(s)

Counsel for Revisionist(s) : Saroj Kumar Yadav

Counsel for Opposite Party(s) : A.S.G.I., R.P.S. Chauhan

Court No. - 86

HON'BLE HARVIR SINGH, J.

1. Heard Sri Niraj Kumar Singh, holding brief of Sri Saroj Kumar Yadav, learned counsel for the revisionists, and Sri R.P.S. Chauhan, learned counsel for the opposite party-Union of India, and perused the record.

2. This Criminal Revision is directed against the impugned cognizance and summoning order dated 19.01.2024 passed by the learned Chief Judicial Magistrate, Gautam Budh Nagar in Complaint Case No. 2462 of 2024 (Union of India vs. Ms Marion Biotech Pvt. Ltd. & Others), under Sections 18(a)(i), 16, 17-A, 17-B, 18-A, 18-B, and punishable under Sections 27(a), 27(b)(i), 27(b)(ii), 27(c), 27(d), 28, 28-A, and 28-B of the Drugs and Cosmetics Act, 1940, Police Station Phase III, Noida, District Gautam Buddh Nagar.

3. The brief facts of the case, are that the revisionists, being directors and officials of M/s. Marion Biotech Pvt. Ltd., (hereinafter referred as Company) they were summoned, pursuant to a complaint filed by the Drugs Inspector, alleging various violations including manufacture/sale of drugs declared "not of standard quality" and further invoking sections related to adulterated and spurious drugs, procedural non-compliance, and liability of company officials. The case is primarily founded on a test analysis report declaring certain samples “not of standard quality,” resulting in proceedings under relevant penal Sections of the Drugs and Cosmetics Act, 1940 (hereinafter referred as “Act”).

4. Learned counsel for the revisionists submits, that the learned Magistrate has taken cognizance and issued summons without proper application of judicial mind. It is contended, that the complaint does not disclose any specific averment, showing that the directors or officers of the company were in charge of and responsible for the conduct of the business of the company at the relevant point of time, as required under Section 34 of the Drugs and Cosmetics Act, 1940. It is further argued,

that the complaint has been filed without obtaining valid sanction, under Section 32 of the Act, and hence, the entire proceedings are vitiated by procedural irregularities.

5. The complaint, it is submitted, does not connect the alleged offences to specific acts of the revisionists; their roles, especially as Directors or functionaries, are not detailed with reference to the overt acts justifying prosecution under the Drugs and Cosmetics Act. The order is called a “manifestation of mechanical appreciation of facts,” reflecting abdication of judicial duty in scrutinizing the record.

6. Learned counsel for the revisionists has submitted that the only finding by test analysis is that, the drug was “not of standard quality.” Nowhere has the sample been found “adulterated” or “spurious,” as defined in Sections 17A and 17B respectively. Thus, invocation of harsher sections (i.e., Sections 17A, 17B, 27a) is not permissible. Each section operates under different factual circumstances, and their criteria are exclusionary.

7. Learned counsel for the revisionists has, next submitted that the test analysis report, relied on, as the foundation of the complaint, lacks compliance with Rule 46 of the Drugs Rules, 1945, as much as, in that, it does not disclose the full protocol, methods, or results in detail. Further, the examination for Diethylene Glycol and Ethylene Glycol in this case was not mandated, but done only upon special request by the Drug Inspector, raising further questions about the standard procedure being adopted.

8. Learned counsel for the revisionists has further submitted, that the sample in question was taken from the warehouse and control room, not from premises stipulated under Section 22 (such as sales/distribution points). This is claimed to be a “glaring procedural irregularity.” Such deviation, the petition asserts, substantially prejudices the accused and vitiates further proceedings, since the Act prescribes these safeguards for fair prosecution.

9. Learned counsel for the revisionists has next submitted, that the complaint is described as “bald and fleeting” in asserting Directors’ and officials’ liability, failing to allege direct involvement, consent, connivance, or neglect required for criminal liability of company officials. Mere designation, the plea holds, does not attract liability; what is needed is proof of active participation or deliberate negligence, either in aid or in furthering of the offence.

10. On the other hand, learned counsel appearing on behalf of the Union of India has submitted, that the Drugs Inspector, operated well within his statutory mandate, collecting samples and initiating prosecution based on objective lab analysis. The complaint lays out the basis for prosecution, and the analytical report constitutes adequate prima facie evidence for the case to proceed. The prosecution submits that the adequacy of evidence or precise procedural compliance can only be tested during trial, not at the summoning stage, as a prima facie case is to be seen at the time of summoning order, while conducting enquiry at that stage by the learned Magistrate.

11. Learned counsel appearing on behalf of the Union of India has further submitted, that having a license to manufacture the certain drugs is not absolute. However, the company has to comply with the conditions of license is more important and, if there is any violation in respect of the conditions given in the license itself, an appropriate case can be made out against the revisionists, as far as, the revisionists have violated the conditions of license, as enumerated in Section 78 of the Act and all those conditions having referred in the counter affidavit filed by the opposite party nos. 1 and 2. Learned counsel for the Union of India has next submitted that the use of Ethylene Glycol in manufacturing the cough syrup was completely prohibited under the applicable British pharmacopoeia. At the time of manufacturing the drugs in question in September 2021, the British pharmacopoeia 2020 was applicable.” Learned counsel for the Union of India has also referred to the quality of samples i.e. the sample in question was manufactured in September 2021

at that time. Indian Pharmacopoeia 2018 was enforced and applicable on manufacturing and export of drugs by the revisionist company.

According to IP 2018, "No peaks corresponding to ethylene glycol and diethylene glycol are obtained in the chromatogram obtained with the test solution" in the determination of DEG and EG in Propylene Glycol.

Ethylene Glycol and Diethylene Glycol was completely prohibited for using in manufacturing of DOK 1 Max Syrup. Whereas, according to the test reports dated 14.01.2023 of RDTL Chandigarh, have substantial amount of Di-Ethylene Glycol & Ethylene Glycol, which is toxic and harmful:

Sample No.	**B. No.**	**Form 13**	**Remarks**
NZSMP/PB/A-022/2022-23	DXS2105	CH/DLS/2022/394	The sample contains Ethylene Glycol **15.87% w/v**
NZSMP/PB/A-023/2022-23	DXS2106	CH/DLS/2022/398	The sample contains Ethylene Glycol **34.28% w/v**
NZSMP/PB/A-024/2022-23	DXS2107	CH/DLS/2022/396	The sample contains Di-Ethylene Glycol **4.09%** & Ethylene Glycol **29.32% w/v**
NZSMP/PB/A-026/2022-23	DXS2108	CH/DLS/2022/397	The sample contains Di-Ethylene Glycol **8.36%** & Ethylene Glycol **24.97% w/v**

The DEG and EG are not the content of PG. Both DEG and EG are toxic and poisonous for health.

Propylene Glycol (PG) is a viscous, colorless liquid. It is almost odourless and has a sweet taste. PG is approved and used as a vehicle/excipient for topical and oral pharmaceutical preparations and cosmetics products.

Ethylene Glycol (EG) and Diethylene Glycol (DEG) are produced from same starting material, Ethylene. EG and DED are used in the production of coolants for engines (brake fluid, antifreeze, lubricants), wallpaper strippers, inks etc., where, most of these products are labelled as "harmful, if swallowed. EG and DEG are toxic to human health, their harmful effect may result in coma, seizure, metabolic acidosis and renal failure.

Ingestion of the glycols lead to systemic toxicity beginning with CNS effects, followed by cardiopulmonary effects, and finally renal failure. The progression of toxic effects can be roughly divided into the following three stages, although overlap is possible. The first phase consists of gastrointestinal symptoms with evidence of inebriation and developing metabolic acidosis. If poisoning is pronounced, patients can progress to a second phase with more severe metabolic acidosis and evidence of a emerging renal injury, which, in the absence of appropriate supportive care, can lead to death.

The US-FDA guidance document dated May 2023 states that "a drug manufacturer must perform the DEG and EG limit test on representative samples of each shipment of each lot of the component and shall ensure that the component contains no more than 0.10% of DEG and EG, before using that component in drug product manufacturing. Further, Bureau of Indian Standard (BIS) also prescribed PG monograph, Food Grade, where Ethylene Glycol is required to be Absent.

12. Learned counsel for the Union of India has further submitted that, at the time of joint investigation conducted by CDSCO and State Drugs Control, U.P. the revisionist company has failed to produce the manufacturer/ supplier Certificate of Analysis of Propylene Glycol in violation of Section 18-B. Purchasing and using of industrial grade/non-pharmaceutical grade propylene glycol from M/s Maya Chemtech India Pvt. Ltd., a firm, which does not hold any drug licence essentially required to sale/distribute ingredients to manufacture a drug, which was used in production of syrup DOC Max 1. Industrial Grade PG is completely prohibited in manufacturing of drugs. During investigation, the company could not produce the manufacturer/supplier certificate provided as CoA.

The Ethylene Glycol and Diethylene Glycol are not available in Propylene Glycol, for the reasons that the same are poisonous and injurious to the human health.

13. The World Health Organization (WHO) had issued Medical Product Alert Nº1/2023 vide Ref.RPQ/REG/ISF/Alert N°1/2023 dated 11.01.2023 related to two contaminated liquid products i.e. AMBRONOL syrup and DOK-1 Max Syrup manufactured by the Applicants Company i.e. M/s Marion Biotech Private Limited and also informed about risk associated with these products, which may results in serious injury or death due to presence of unacceptable amount of di-ethylene Glycol (DEG) and/or Ethylene Glycol (EG) as contaminants with the use of industrial grade/non-pharmaceutical grade propylene glycol and Glycerin and also submitted, that the Applicants/Accused Persons used the industrial grade/non-pharmaceutical grade propylene glycol and Glycerin for manufacturing the drugs in question. Hence, the Applicants/Accused Persons manufactured the Adulterated and Spurious drugs. Further, It is submitted that, if the Applicants/Accused Persons are not satisfied with the Govt. Analyst Report, then they have to avail the opportunity to challenge the Govt. Analyst Report, but they have not challenged the Govt. Analyst Report, within a stipulated time of 28 days, as per Drugs & Cosmetics Act, 1940. As such the opposite party filed the present complaint along with the documentary evidence, before the learned Trial Court with the panel section of Drugs and Cosmetics Act & Rules framed there under**.** Learned counsel for the Union of India emphasized the fact and laid stress upon the DOK-I Max syrup, as manufactured by the revisionists was found poisonous in Uzbekistan, which resulted in death of more than 18 children. Learned counsel for the Union of India argued that, at the time of passing of the cognizance/summoning order, the learned Magistrate has come to the conclusion that, a prima-facie case is made out against the accused persons and the learned Magistrate is not required to conduct the mini trial at this stage and further submitted that the cognizance/summoning order passed by the learned Magistrate is in accordance with law and calls for no interference by this Court, as the revisionist will have ample opportunity to redress themselves at the time of framing of the charge and the stage of charge is yet to come. Learned counsel for the Union of

India has further submitted that the accused persons, revisionist herein are the Directors, Officers and the Employees of the company and therefore, they are closely associated with day to day working of the company and in the absence of the Directors and the responsible persons, there would be no existence of the company, as far as functionaries and operational activities are concerned. Learned counsel for the Union of India has next submitted that, it is not the case of the revisionists, that the revisionists are not at all aware of the operations and business being conducted in the company, as they work for gain and profit and enjoy the profit accordingly. Learned counsel for the Union of India has next submitted that a narrow interpretation of regulatory provisions would defeat the public purpose underlying the Act. Enforcement of public health laws cannot be thwarted by technical objections relating to mere technicalities. Learned counsel for the Union of India has further submitted that the action taken by the complainant, strengthens public health enforcement by curbing technical defences in regulatory prosecutions. Learned counsel for the Union of India has further submitted that in view of the fact that substandard drugs encounter a major stringent issue for the health system and the violations and deviations cannot be ignored. The matter is at the initial stage, and there are specific allegations of the creation of forged test lab reports to claim substandard drugs of standard quality; those being subject matter of trial, therefore, on perusal of the contents of the impugned summoning order, the ingredients of commission of cognizable offence are prima- facie made out. Learned counsel for the Union of India has next submitted that the allegations made in the complaint, do clearly constitute a cognizable offence justifying the registration of complaint and the investigation thereon, and this does not fall under any of the categories of cases formulated by the Supreme Court in ***State of Haryana v. Bhajan Lal: AIR 1992 SC 604,*** as argued by the revisionists, calling for the exercise of extraordinary or inherent powers of the High Court to quash the impugned summoning order in the case. Otherwise also, it is not the case of the revisionists that, even if the

allegations made in the complaint, are taken at their face value and accepted in their entirety, do not prima facie constitute any offence or make out a case, against the accused even then sufficient material is available to summon the accused persons. The revisionists have also not pleaded any express bar engrafted in any provisions of the Code or any other law, including the Drugs and Cosmetics Act, to the institution and continuance of the proceedings, therefore, all the revisionists have been summoned rightly and the revision is devoid of merits, and hence liable to be dismissed.

14. Learned counsel for the Union of India has further submitted, that the process of collecting, sealing, sending the sample for analysis, and reporting were as per prescribed norms. The technicalities raised about sampling location or manner are characterized, as not having any procedural fatal irregularity, especially in criminal regulatory prosecutions governed by public safety standards.

15. Learned counsel for the Union of India has next submitted that the learned Magistrate, upon perusal of the complaint and supporting documents, found sufficient grounds to proceed against the revisionists. The requirement, at this stage is not to establish guilt, but to put the process in motion, when the complaint and annexed evidence shows legal and factual plausibility of the alleged offences to be tried upon the revisionists, under relevant sections under the Drugs and Cosmetics Act, 1940.

16. Learned counsel for the Union of India has further submitted that, by statutory provisions, those responsible for the company’s affairs i.e. Directors, senior functionaries are within the sweep of Section 34 for offences committed under the Act, and they are wholly and fully responsible for conduct of the business of the company. The prosecution maintains that, vicarious liability arises due to any negligent act and omission committed in discharge of the duty and carrying out the business for the pecuniary gain of the company. Thus liability in civil

and criminal prosecutions are different and may stand on different footings.

17. Learned counsel for the Union of India has next submitted that the application of various penal section is justified based on the overall conduct, findings, and the entire material collected during the course of investigation and documentation. The details of which section finally applies, is a matter for evidence and framing of charge and a prima facie case is to be seen at the time of cognizance and summoning of the accused persons.

18. Learned counsel for the Union of India has further submitted that the detailed appreciation can be finally conducted and concluded during the course of trial and the Magistrate's discretion at summoning stage should not be lightly interfered with, unless there is palpable illegality. In the present case, a prima facie case has been made out against the accused persons, at this stage of summoning the accused/revisionists and the order calls for no interference by this Court.

19. Learned counsel for the revisionists relied upon the following judgments of Hon'ble Supreme Court:-

(i). M/s GHCL Employees Stock Option Trust vs M/s India Infoline Ltd: (2013) 4 SCC 505.

(ii) M/s Pepsi Foods Ltd. & Anr. vs Special Judicial Magistrate & Ors.: (1998) 5 SCC 749.

(iii) Lalankumar Singh vs The State of Maharashtra: 2022 SCC OnLine SC 1383.

(iv) Raj Kishan vs State: 1959 SCC OnLine All 152.

(v) Dharam Deo Gupta vs State: All. HC Crl. Rev. No. 143/1956.

(vi) Din Dayal vs State: All. HC Crl. Rev. No. 752/1954.

(vii) State of Maharashtra vs Ghanshyam K. Zaveri & Anr.: (1993) 1 SCC 526.

(viii) Mohd. Shabir vs State of Maharashtra: (1979) 1 SCC 568.

(ix) Drugs Inspector vs Chimanlal & Co. & Ors : AIR 1965 SC 1958.

(x) M/s Medicamen Biotech Ltd. & Anr. vs Rubina Bose, Drug Inspector: (2008) 7 SCC 196.

20. Learned counsel for the opposite party no. 2-Union of India relied upon the following judgments of Hon'ble Supreme Court as well as Hon'ble High Courts:-

(i) Amit Mittal and Another Vs. State of U.P. And Another in Application U/s. 482 Cr.P.C. No. 22832 of 2015.

(ii) State of Maharashtra Vs. Ghanshyam K. Zaveri and Another : 2000 SCC OnLine Bom 748.

(iii) Amit Kapoor Vs. Ramesh Chander: (2012) 9 SCC 460.

(iv) Gulam Mustafa Vs. State of Karnataka : 2023 SCC OnLine SC 603.

(v) CBI Vs. Aryan Singh: 2023 SCC OnLine SC 379.

(vi) Abhishek Vs. State of M.P. : 2023 SCC OnLine SC 1083.

(vii) Sanofi India Ltd. Vs. Union of India: (2021) 3 HCC (Del) 691.

(viii) State of Orrisa Vs. Debendra Nath Padhi, Appeal (Crl.) No. 497 of 2001 (SC)

21. Having considered the rival contentions and after going through the order of cognizance and summoning, it would be appropriate to look into the relevant sections of the Drugs and Cosmetics Act, 1940,ds as enumerated below:-

"16. Standards of quality.—*(1) For the purposes of this Chapter, the expression "standard quality" means—*

(a) in relation to a drug, that the drug complies with the standard set out in 5[the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) The [Central Government], after consultation with the Board and after giving by notification in the Official Gazette not less than

three months ' notice of its intention so to do, may by a like notification add to or otherwise amend 5[the Second Schedule] for the purposes of this Chapter, and thereupon 5[the Second Schedule] shall be deemed to be amended accordingly.

***17. Misbranded drugs.**—For the purposes of this Chapter, a drug shall be deemed to be misbranded,—*

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

***17A. Adulterated drugs.**— For the purposes of this Chapter, a drug shall be deemed to be adulterated,—*

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

***17B. Spurious drugs.—**For the purposes of this Chapter, a drug shall be deemed to be spurious,—*

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

17C. Misbranded cosmetics.—*For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded,—*

(a) if it contains a colour which is not prescribed; or

(b) if it is not labelled in the prescribed manner; or

(c) if the label or container or anything accompanying the cosmetic bears any state- ment which is false or misleading in any particular.

17D. Spurious cosmetics.—*For the purposes of this Chapter, a cosmetic shall be deemed to be spurious,—*

(a) if it is manufactured under a name which belongs to another cosmetic; or

(b) if it is an imitation of, or a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic unless it is plainly and conspicuously marked so as to re veal its true character and its lack of identity with such other cosmetic; or

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) if it purports to be the product of a manufacurer of whom it is not truly a product.]

[17E. Adulterated cosmetics. *— For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated,—*

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.]

18. Prohibition of manufacture and sale of certain drugs and cosmetics.—*From such 2date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—*

(a) 3[manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or

distribute—

[(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

[(ii) any cosmetic which is not of a standard quality or is misbranded, adulterated or

spurious;]]

[(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof 3[the true formula or list of active ingredients contained in it together with the quantities thereof];]

(iv) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims 7[to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

[(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;]

(b) [sell or stock or exhibit or offer for sale,] or distribute any drug 9[or cosmetic] which has been been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) 3[manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute any drug 9[or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis :

Provided further that the [Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the [manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale] or distribution of any drug or class of drugs not being of standard quality.

***18A. Disclosure of the name of the manufacturer, etc.**—Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.*

***18B. Maintenance of records and furnishing of information.**—Every person holding a licence under clause (c) of section 18 shall*

keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

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 6[17B and 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 grevious hurt within the meaning of section 320 o f the Indian Penal Code (45 of 1860) solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be 7[punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more]:

[Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or, spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

Explanation.—For the purposes of the second proviso, the expression "relative" means—

(i) spouse of the deceased person; or

(ii) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or

(iii) parent of the minor victim; or

(iv) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

(v) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of his death,—

(a) the parent; or

(b) a minor brother or an unmarried sister; or

(c) a widowed daughter-in-law; or

(d) a widowed sister; or

(e) a minor child of a pre-deceased son; or

(f) a minor child of a pre-deceased daughter where no parent of the child is alive; or

(g) the paternal grandparent if no parent of the member is alive;]

(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 1[not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more]:

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 2[less than three years and of fine of less than one lakh 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 3[not less than seven years but which may extend to imprisonment for life and with fine which shall not be three lakh rupees or three times the value of the drugs confiscated, whichever is more]:

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 4[less than seven years but not less than three years and of fine of less than one lakh rupees];

(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 5[and with fine which shall not be less than twenty 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.

27A. Penalty for manufacture, sale, etc., of cosmetics 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—*

(i) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with

fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics confiscated, whichever is more;

(ii) any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both.

28. Penalty for non-disclosure of the name of the manufacturer, etc.*—Whoever contravenes the provisions of section 18A 2[or section 24] shall be punishable with imprisonment for a term which may extend to one year, or 3[with fine which shall not be less than twenty thousand rupees or with both.*

28A. Penalty for not keeping documents, etc., and for non-disclosure of information.—Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or [with fine which shall not be less than twenty thousand rupees or with both].

28B. Penalty for manufacture, etc., of drugs or cosmetics in contravention of section 26A.*—Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.*

34. Offences by companies.*—(1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:*

Provided that nothing contained in this sub -section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub -section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section—

(a) "company" means a body corporate, and includes a firm or other association of individuals;

and

(b) “director” in relation to a firm means a partner in the firm.”

22. Besides the above provisions of the Act, the plea of the revisionists, alleging various violations including manufacture/sale of drugs declared "not of standard quality" and further invoking sections related to adulterated and spurious drugs, procedural non-compliance, and liability of company officials and that the learned Magistrate has taken cognizance and issued summons, without proper application of judicial mind and the complaint has been filed without obtaining valid sanction, under Section 32 of the Act. The test analysis report, relied on, as the foundation of the complaint, lacks compliance with Rule 46 of the Drugs Rules, 1945 etc. are hereby discussed and examined in the light of the arguments raised from each side, the statutory provisions and the law laid down on the subjects.

23. After going through the record, it can be seen that the Drugs Inspector, operated well within his statutory mandate, collecting samples and initiating prosecution based on objective lab analysis. The complaint lays out the basis for prosecution, and the analytical report constitutes adequate prima facie evidence for the case to proceed in accordance with law. It is further noted that, having a license to manufacture the certain drugs is not sufficient and absolute. However, the company has to comply with the conditions of license, is equally important and, if there is any violation in respect of the conditions, given in the license itself, an appropriate case can be made out against the revisionists, as such the revisionists have violated the conditions of license, as enumerated in Section 78 of the Act. The use of Ethylene Glycol in manufacturing the cough syrup was completely prohibited under the applicable British pharmacopoeia. At the time of manufacturing the drugs in question in September 2021 the British pharmacopoeia 2020 was applicable and the sample in question was manufactured

in September 2021, at that time, Indian Pharmacopoeia 2018 was enforced and made applicable on manufacturing and export of drugs by the revisionist company.

24. It has also been found that, at the time of joint investigation conducted by CDSCO and State Drugs Control, U.P. the revisionist company has failed to produce the manufacturer/supplier Certificate of Analysis of Propylene Glycol in violation of Section 18-B. Since purchasing and using of industrial grade/non-pharmaceutical grade propylene glycol from M/s Maya Chemtech India Pvt. Ltd., a firm, which does not hold any drug licence essentially required to sale/distribute ingredients to manufacture a drug, was used in production of syrup DOC Max 1. The DOK-I Max syrup manufactured by the revisionists, was found poisonous in Uzbekistan, which resulted in death of more than 18 children and at the time of passing of the cognizance/summoning order, the learned Magistrate has come to the conclusion that, a prima-facie case is made out against the accused persons and the learned Magistrate is not required to conduct the mini trial at this stage of summoning the accused persons.

25. The accused persons, revisionist herein are the Directors, Officers and the Employees of the company and therefore, they are closely associated with day to day working of the company and in the absence of the Directors and the responsible persons, there would be no existence of the company, as far as functionaries and operational activities are concerned and a narrow interpretation of regulatory provisions, would defeat the public purpose underlying the Act. Enforcement of public health laws cannot be thwarted by technical objections, relating to mere technicalities and in view of the fact, that substandard drugs encounter a major stringent issue for the health system and the violations and deviations cannot be ignored.

26. It can also be seen that, the process of collecting, sealing, sending the sample for analysis, and reporting were completed as per prescribed norms. The technicalities raised about sampling location or manner as characterized, are not having any procedural fatal irregularity, especially in criminal regulatory prosecutions governed by public safety standards and at this stage is not to establish guilt, but to put the process in motion, when the complaint and annexed evidence, shows legal and factual plausibility of the alleged offences to be tried upon relevant sections under the Drugs and Cosmetics Act, 1940.

27. It can further be seen that, by statutory provisions, those responsible for the company's affairs i.e. Directors, senior functionaries are within the sweep of Section 34 for offences committed under the Act, and they are wholly and fully responsible for conduct of the business of the company and mere statement that the Directors of the company have nothing to do with the business of the company and the day to day working, leads nowhere.

28. Having considered the entire facts and circumstances of the case and the law, as laid down by the Hon'ble Supreme Court and the High Courts, the case of the revisionists is different, and the facts and grounds raised in the instant revision are mere technicalities, and no glaring mistake or gross irregularity has been noted in the summoning order. Therefore, the law, as cited by the revisionists does not help them, in the given circumstances and the cognizance/summoning order passed by the learned Magistrate is in accordance with law and calls for no interference by this Court, furthermore, the revisionist will have ample opportunity to redress themselves at the time of framing of the charge and the stage of charge is yet to come. Thus, there appears to be no illegality or infirmity in the summoning order passed by the learned Magistrate. All Criminal Revisions No. 4884 of 2024, 5442 of 2025, 5443 of

2025 and 5444 of 2025 are devoid of merit and are liable to be dismissed. Hence, ***dismissed***.

29. A copy of this order be kept in each of the file of the above connected revisions.

(Harvir Singh,J.)

January 14, 2026
Vikram