IN THE HIGH COURT FOR THE STATES OF PUNJAB AND HARYANA AT CHANDIGARH

CNR No: PHHC010328912026
2026:PHHC:123774

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CRM-M-11321-2015 (O&M)
Date of decision : 14.09.2026

M/s Super Cardio Devices Private Limited and others **...Petitioners**

Versus

State of Haryana **...Respondent**

CORAM: HON'BLE MRS. JUSTICE MANISHA BATRA

Present:- Mr. Sushant Mahapatra, Advocate and
Mr. Sanjeev Kumar, Advocate
for the petitioners.

Mr. Ashok Kumar Khubbar, Addl. A.G., Haryana.

MANISHA BATRA, J.*(Oral)*

1. The present petition has been filed under Section 482 Cr.P.C. *(which corresponds to Section 528 of BNSS, 2023)* seeking quashing of complaint dated 16.07.2013 titled ***Haryana State through Drugs Control Officer, Jhajjar v. M/s Super Cardio Devices Pvt. Ltd. and others***, registered as Complaint No.1231, filed under Sections 18(c) read with Sections 27(b)(ii), 28B, 28A and 27(d) of the Drugs and Cosmetics Act, 1940 *(for short 'the Act, 1940)* and Rules 74 and 78 read with Schedules J, L-I and M of the Drugs and Cosmetics Rules, 1945, pending before the Court of learned Chief Judicial Magistrate, Jhajjar, along with the consequential proceedings, including the summoning order dated 16.07.2013 and order dated 29.10.2014 passed by the learned Sessions Judge, Jhajjar, whereby the revision petition preferred against the summoning order was dismissed.

2. The facts, as borne out from the complaint, are that petitioner No.1-M/s Super Cardio Devices Pvt. Ltd. is a company having its premises at 105, MIE Part-A, Bahadurgarh, District Jhajjar, Haryana. Petitioner No.2 was stated to be its Director-cum-Manufacturing Chemist and petitioner No.3 as its Director. The complainant, i.e. the Drugs Control Officer, Jhajjar, received information regarding manufacturing of **Heart Lung Pack** by petitioner No.1 without a valid drug manufacturing licence. An inspection of the premises was carried out on 28.10.2010, where manufacturing activity relating to Heart Lung Pack was found to be going on. The complainant took samples of the product and completed the requisite proceedings under the Act and Rules. The State subsequently treated the product as a drug and alleged that the petitioners were manufacturing the same without the requisite manufacturing licence. As per the further allegations, on a subsequent inspection conducted on 18.04.2012, three pieces of Heart Lung Pack were taken as samples from the finished goods store and the requisite forms were prepared. The complainant thereafter sought permission from the State Drugs Controller, Haryana, for launching prosecution against the petitioner, which was so granted. The complaint was accordingly filed before the Court of learned Chief Judicial Magistrate, Jhajjar, who vide order dated 16.07.2013 summoned the petitioners for the offences alleged in the complaint. Aggrieved from the same, petitioner No. 2 filed a revision petition against the impugned summoning order but the same was dismissed by the Court of learned Sessions Judge, Jhajjar, vide order dated 29.10.2014. Hence, the present petition.

3. It is argued by learned counsel for the petitioners that the impugned complaint as well as the summoning order are not sustainable in the

eyes of law. It is submitted that the entire prosecution is based on the assumption that Heart Lung Pack is a "drug" within the meaning of Section 3(b)(iv) of the Act, 1940, whereas the statutory requirement for bringing a medical device within the definition of drug has not been satisfied in the present case. It is further argued that Section 3(b)(iv) requires the Central Government to specify the concerned device by notification in the Official Gazette, after consultation with the Drugs Technical Advisory Board. This requirement assumes importance because the Heart Lung Pack was never specifically notified as a drug in the Official Gazette. Learned counsel referred to the notification dated 06.10.2005 issued by the Central Government under Section 3(b)(iv) to contend that the said notification specified ten categories of medical devices, including "Catheters", but did not mention Heart Lung Pack. The relevant notification placed on record specifically mentions Cardiac Stents, Drug Eluting Stents, Catheters, Intra Ocular Lenses, IV Cannulae, Bone Cements, Heart Valves, Scalp Vein Sets, Orthopaedic Implants and Internal Prosthetic Replacements. He further argued that Heart Lung Pack cannot simply be treated as a "catheter" merely because the word "Catheters" finds mention in the 2005 notification. He referred to the material placed on record explaining that the Heart Lung Pack is a customised tubing pack/extracorporeal circuit which carries solutions during cardiac surgery and is not inserted into the body. The cannulae and catheters which are inserted into the body are distinct from the Heart Lung Pack.

4. While referring to the clarification dated 20.03.2009, on which the prosecution principally relies, learned counsel for the petitioners has argued that although Heart Lung Pack was mentioned at serial No.15 in the said

clarification, yet, the clarification itself had no statutory force as it was not an Official Gazette notification under Section 3(b)(iv). The document merely listed 19 medical devices stated to be covered under the Drugs and Cosmetics Act and Rules. More importantly, learned counsel argued that the said clarification was immediately followed by the CDSCO circular dated 05.05.2009. The circular specifically stated that the matter had been referred to the Ministry of Health for concurrence and approval and that the final decision would be taken after such approval. In the meantime, the circular directed that the practices prevailing prior to 20.03.2009 should continue until further orders of the Ministry. It is, thus, argued that the clarification dated 20.03.2009 could not be treated as a final or operative notification bringing Heart Lung Pack within the definition of "drug". Moreso, out of the 19 medical devices referred to in the clarification dated 20.03.2009, 11 articles were subsequently categorised under already notified medical devices, whereas Heart Lung Pack was one of the eight devices which were left out. The subsequent letter dated 07.09.2012 issued by the Central Drugs Standard Control Organisation cannot cure this defect. He pointed out that the said letter merely stated that Heart Lung Packs are covered under the categories of "Catheter/Disposable Perfusion Set" and that those categories were notified under Section 3(b)(iv). However, the said letter was only an administrative communication and could not take the place of a statutory notification in the Official Gazette.

5. Learned counsel for the petitioners, while referring to the proceedings before the Expert Committee and the communication dated 20.05.2015 issued by the Director General of Health Services, has further argued that the Expert Committee had opined that "Heart Lung Pack is not a

drug but it is a medical device". It is submitted that subsequent material is relevant because it shows that even the Central authorities did not regard the classification of Heart Lung Pack as an obvious or settled matter. The first alleged offence relates to the inspection dated 28.10.2010. Therefore, the legal position existing on that date would be relevant. A subsequent communication issued in 2012 could not retrospectively make the manufacture of the product in 2010 an offence. The application made by the petitioners for a drug manufacturing licence cannot be treated as an admission that Heart Lung Pack was a drug. The application was made in the backdrop of the regulatory uncertainty and in an attempt to comply with the directions of the authorities.

6. It is further argued that the learned Chief Judicial Magistrate had passed the summoning order mechanically without considering the basic question whether Heart Lung Pack was legally a drug at all. The learned Sessions Judge also failed to consider the effect of the documents showing that the product had not been notified as a drug. While submitting that the basic ingredient of the alleged offences, i.e. manufacturing of a "drug" without a licence, was absent and continuation of the criminal proceedings would amount to abuse of the process of law, it is urged that the petition deserves to be allowed and the impugned complaint and summoning order along with all the subsequent proceedings having emanated therefrom are liable to be quashed.

7. *Per contra*, learned State counsel has opposed the petition and argued that the prosecution has rightly been launched against the petitioners. He argued that the Gazette Notification dated 06.10.2005 specifically notified "Catheters" as drugs under Section 3(b)(iv) of the Act, 1940. The said article falls within the category of catheter/disposable perfusion set and, therefore,

falls within the notified category. Learned State counsel further relied upon the clarification dated 20.03.2009 issued by the office of the DCGI, wherein Heart Lung Pack was specifically mentioned at serial No.15 amongst the medical devices covered under the Drugs and Cosmetics Act and Rules. He has also referred to communication dated 07.09.2012 issued by the Central Drugs Standard Control Organisation. Learned State counsel argued that the said communication specifically records that Heart Lung Packs are covered under the categories of Catheter/Disposable Perfusion Set, which are notified under Section 3(b)(iv), and therefore the State authorities were justified in taking action against the petitioners. It is further argued that the petitioners were found manufacturing the product without a valid drug manufacturing licence. Samples were taken during inspection and requisite proceedings were conducted under the Act and Rules. The petitioners themselves subsequently applied for a drug manufacturing licence, which also shows that they were aware of the regulatory requirement. The question whether the particular Heart Lung Pack is a catheter or a disposable perfusion set is a matter requiring evidence and technical examination. Such a question, according to learned counsel, cannot be finally decided by this Court in exercise of its inherent jurisdiction under Section 482 Cr.P.C. Hence, it is urged that the petition is liable to be dismissed.

8. This Court has heard the rival submissions of learned counsel for the parties, besides going through the material placed on record.

9. The principal question which arises for consideration is whether, on the date of the alleged manufacture, i.e. 28.10.2010, the **Heart Lung Pack** manufactured by the petitioners could legally be treated as a “drug” within the meaning of Section 3(b)(iv) of the Act, 1940, so as to attract the requirement of

a manufacturing licence and the penal provisions of the Act, 1940? Section 3(b)(iv) of the Act brings within the definition of "drug" such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals as may be specified by the Central Government by notification in the Official Gazette, after consultation with the Board. Thus, in case of a medical device, mere use of the device for a medical purpose does not, by itself, make it a "drug" within the meaning of the Act. The statutory requirement of specification by the Central Government through notification in the Official Gazette assumes significance before the penal provisions of the Act can be invoked.

10. In the present case, the prosecution relies upon the notification dated 06.10.2005 issued by the Central Government. A perusal of the said notification shows that various medical devices were specified therein, including "Catheters". However, Heart Lung Pack is not specifically mentioned in the said notification. The case of the petitioners, as emerging from the material on record, is also that Heart Lung Pack is an extracorporeal circuit/customized tubing pack which is used for carrying solutions during surgery and is not itself inserted into the body, whereas a catheter is a distinct device which is inserted into the body. The petitioners have accordingly sought to distinguish Heart Lung Pack from the category of "Catheters".

11. This distinction assumes importance because the prosecution cannot proceed merely on the basis that Heart Lung Pack is a medical device. What has to be shown is that the particular device was covered by the statutory notification so as to fall within Section 3(b)(iv) of the Act, 1940 at the relevant time. The requirement of a notification in the Official Gazette is, therefore, not

a mere procedural formality, but is the statutory basis for bringing a particular device within the definition of "drug". Reference in this regard can be made to ***Biogenetic Drugs (P) Ltd. v. State of Himachal Pradesh and others, 2025:HHC:20463***, wherein the Himachal High Court held that Section 3(b)(iv) specifically requires a device to be specified by the Central Government by notification in the Official Gazette. The Court further observed that regulatory requirements could not be created merely through an administrative order or office instruction in the absence of statutory authority. The respondents, however, rely upon the clarification dated 20.03.2009 issued by the CDSCO, wherein Heart Lung Pack finds mention at serial No.15 amongst the nineteen sterile medical devices. The said document may certainly indicate the stand taken by the department regarding the regulatory treatment of such devices. However, the said clarification is admittedly not a notification issued in the Official Gazette by the Central Government under Section 3(b)(iv) of the Act, 1940. The distinction between a statutory notification and an administrative clarification cannot be lost sight of when the consequence sought to be imposed is criminal in nature.

12. The aforesaid position becomes still more significant in view of the subsequent circular dated 05.05.2009 issued by the CDSCO. The said circular itself records that the clarification dated 20.03.2009 had been referred to the Ministry of Health and Family Welfare for concurrence/approval and that, till further orders, the prevailing practice before 20.03.2009 was to continue. Thus, the material placed before the Court does not disclose a clear and unequivocal statutory position regarding the inclusion of Heart Lung Pack under the Act during the relevant period. The principle laid down in ***Kirti***

Kumar Jayantilal Patel and others v. State of Maharashtra, MANU/MH/1218/2023 is relevant in this regard. In that case also, the Bombay High Court was dealing with prosecution under the Drugs and Cosmetics Act and held that a manufacturer could not be faulted for not complying with a standard which had not been prescribed at the time when the drug was manufactured. The Court ultimately quashed the criminal proceedings, holding that the action initiated against the manufacturer was not in accordance with law.

13. Coming to the letter dated 07.09.2012 relied upon by the respondents, the said communication states that Heart Lung Packs are covered under the categories of “Catheter/Disposable Perfusion Set”. The difficulty, however, is that the said communication was issued much after the alleged manufacture dated 28.10.2010. It is also an administrative communication and not a notification in the Official Gazette issued under Section 3(b)(iv). Consequently, the said letter may reflect the department's subsequent understanding of the product, but it cannot by itself retrospectively create the statutory foundation for criminal liability for an act allegedly committed in the year 2010. The subsequent material placed on record also does not resolve the issue in favour of the prosecution with the degree of certainty required in a criminal case. In fact, the later consideration of the issue by the Expert Committee and the departmental communications show that the precise classification of Heart Lung Pack itself remained a matter requiring examination. The material on record records the opinion that Heart Lung Pack is a medical device, while the question of its classification under the notified categories was still required to be considered by the competent authority. Thus,

the subsequent material rather demonstrates that the precise statutory classification of the product was not an entirely settled matter. It is, therefore, necessary to keep in view the distinction between a medical device being capable of being regulated and that device being brought within the definition of "drug" under Section 3(b)(iv). The former, by itself, is not sufficient for imposing criminal liability. In the present case, the prosecution has to demonstrate that Heart Lung Pack was covered by a valid statutory notification at the relevant point of time. The mere reference to Heart Lung Pack in a subsequent departmental clarification or administrative communication cannot substitute the requirement prescribed by the statute. The principle of strict construction of penal provisions also assumes relevance. In ***Tolaram Relumal v. State of Bombay, AIR 1954 SC 496***, the Hon'ble Supreme Court reiterated that where a penal provision is capable of more than one reasonable interpretation, a construction exposing a person to penal consequences cannot be adopted unless the statutory requirement is clearly satisfied.

14. In the present case, therefore, the issue is not whether the petitioners possessed a manufacturing facility, whether the product was used in medical procedures, or whether the department subsequently considered such product to be covered under the regulatory regime. Rather, the foundational issue is whether the product manufactured by the petitioners on 28.10.2010 was, in law, a "drug" within Section 3(b)(iv) on that date. The 06.10.2005 notification does not specifically mention Heart Lung Pack; the clarification dated 20.03.2009 is not an Official Gazette notification; the circular dated 05.05.2009 itself indicates that the matter was awaiting further consideration;

and the letter dated 07.09.2012 is subsequent to the alleged offence and is only an administrative communication.

15. It is true that the respondents seek to place Heart Lung Pack within the notified categories of “Catheters” or “Disposable Perfusion Sets”. However, whether the product actually falls within any such notified category cannot be assumed merely from the nomenclature used in a subsequent departmental letter, particularly when the petitioners have specifically asserted that Heart Lung Pack is a distinct extracorporeal tubing system and the material on record itself reflects that its precise classification was subsequently examined by the authorities. No clear statutory notification which brought the particular product within Section 3(b)(iv) on the relevant date has been produced before this Court. The ratio of law laid down in ***Kirti Kumar Jayantilal Patel’s case (supra)*** also assumes significance at this stage. The Court therein recognised that criminal prosecution under the Drugs and Cosmetics Act cannot be sustained on the basis of a requirement which was not legally applicable to the manufacturer at the time of manufacture. The same principle applies here in the limited sense that a subsequent administrative understanding cannot be used to retrospectively fasten criminal liability upon the petitioners for manufacture undertaken at a time when the statutory coverage of the product itself was not clearly established.

16. It is also relevant that the entire prosecution in the present case proceeds on the basic premise that Heart Lung Pack was a “drug” requiring a licence for its manufacture. The allegation regarding manufacture without licence and the consequential allegations under the provisions of the Drugs and Cosmetics Act are dependent upon that foundational premise. If the product

itself is not shown to have been brought within the definition of “drug” under Section 3(b)(iv) in accordance with the statutory requirement, the very basis for invoking the penal provisions of the Act against the petitioners becomes unsustainable.

17. This Court is conscious that at the stage of considering a petition under Section 482 Cr.P.C., it is ordinarily not required to undertake an appreciation of evidence or conduct a mini-trial. However, the present case does not require such an exercise. The issue arising for consideration is essentially one concerning the legal applicability of the statutory regime to the product in question and the documents relied upon by both sides are themselves part of the record. Where the foundational requirement for attracting the penal provision is absent or legally doubtful on the admitted material, continuation of the criminal proceedings would serve no useful purpose.

18. Consequently, without expressing any opinion on the general regulatory status of Heart Lung Pack as a medical device, this Court finds that the prosecution has failed to establish the necessary statutory foundation for treating the product manufactured by the petitioners on the relevant date as a “drug” under Section 3(b)(iv) of the Act, 1940. The subsequent administrative communications, including the letter dated 07.09.2012, cannot retrospectively supply the requirement of a statutory notification so as to sustain criminal liability for the alleged manufacture in the year 2010. In these circumstances, permitting the criminal proceedings to continue against the petitioners would amount to permitting a prosecution without the foundational ingredient necessary to attract the penal provisions of the Act, 1940. The continuation of such proceedings would, therefore, amount to an abuse of the process of law

and calls for interference by this Court in exercise of its inherent jurisdiction under Section 482 Cr.P.C.

19. Accordingly, the present petition is allowed and impugned Complaint No.1231 dated 16.07.2013, the summoning order dated 16.07.2013 passed by the learned trial Court and the order dated 29.10.2014 passed by the learned Additional Sessions Judge, Jhajjar, are hereby quashed, along with all consequential proceedings arising therefrom.

14.09.2026 **(MANISHA BATRA)**
Waseem R. Ansari **JUDGE**

Whether speaking/reasoned *Yes/No*

Whether reportable *Yes/No*