IN THE HIGH COURT OF PUNJAB AND HARYANA AT CHANDIGARH

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CRR No.1270 of 2016 (O&M)
Reserved on: 20.09.2023
Pronounced on: 29.09.2023

Bhupinder Singh and others **.....Petitioners**

Vs.

State of Haryana through Drugs Control Officer, Ambala City, Haryana **.....Respondent**

CORAM: - HON'BLE MR. JUSTICE DEEPAK GUPTA

Present: - Mr. Sandeep Wadhawan, Advocate and
Mr. Suvir Tandon, Advocate for the petitioners.

Mr. Vipul Sherwal, AAG, Haryana.

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DEEPAK GUPTA, J.

By way of present revision, petitioners have assailed the order dated 29.01.2016, whereby they have been charge-sheeted by the Court of learned Special Judge, Ambala under Section 27(b)(ii) and 28 of the Drugs and Cosmetics Act, 1940 (For short, `the Act'), in Criminal Complaint No.53 dated 10.03.2012 *(Annexure P-3)* filed by the State of Haryana through Drugs Control Officer, Ambala against M/s Abdiel Pharmaceuticals and its two directors Bhupinder Singh & Harpreet Singh *(petitioners herein)*.

2. It is contended by learned counsel for the petitioners that petitioner No.3 (M/s Abdiel Pharmaceuticals) firm is registered manufacturer of dietary food supplements in the State of Haryana and that as per Schedule K of the Drugs and Cosmetics Rules, 1945, (for short, `the Rules'), the dietary food supplements do not come within the definition of drugs being exempted under Rule 123 of the said Rules. However, on 22.10.2009, the complainant visited the premises of petitioner No.3 and took certain samples on the ground that it was manufacturing drugs, without possessing the drug licence to manufacture the same. Petitioners have given

description of five samples, which were seized by the complainant from their premises and submit that on analysis of the samples by the government analyst, the same were found to be confirming to the standards but it has been alleged by the complainant that the samples were of allopathic drugs, regarding which petitioner No.3 does not have any drug licence and, so, it has committed offences under Section 18 (c) & 18A of the Act, punishable under Sections 27 and 28 of the Act and so, complaint Annexure P.3 was filed before learned Chief Judicial Magistrate, Ambala City, who initially framed the charge on 09.10.2015 but later on chose to commit the case and then learned Special Judge framed the charges by way of the impugned order.

3. Learned counsel for the petitioners has referred to Rule 123 of the Rules and relevant portion of Schedule K to fortify his submission that samples taken by the complainant were of the dietary products and not of drugs. Learned counsel further submitted that the complaint was filed on 10.03.2012, i.e., much after the expiry date of the alleged drugs in question and so, valuable rights of the petitioners to challenge the report in the Court of law has been violated, as they could not claim any opportunity for re-test of the drugs on account of filing of the complaint after the expiry period.

4. It is further contended that petitioners had duly submitted reply to the show cause notice within 20 days of the show cause notice as per Section 25(4) of the Act and as per that reply, it was claimed that petitioner was only manufacturing food supplements, which fact was printed on the cartons of each product and that those were dietary supplements and not meant for medicinal use and so, no provisions of the Act were violated. Learned counsel has referred to Section 25 of the Act besides Rules 6 and Rule 46 of the Rules in this regard and has relied upon ***M/s Medicamen***

Biotech Ltd. & Anr. Vs. Rubina Bose, Drug Inspector, 2008(2) R.C.R. (Criminal) 496 *and* ***Balwinderjit Singh and another Vs. State of Punjab and another, 2014(2) Drugs Cases (DC) 184.***

5. (i) Opposing the afore-said petition, learned State Counsel submits that nine samples of drugs were seized for analysis on the spot from petitioner No.3 through petitioners No.1 and 2 on 22.10.2009 by the team of officials and though the drugs were found to be of standard quality by the government analyst, but the same were drugs within the meaning of Section 3(b) of the Act and not dietary/food supplements, as claimed by the petitioners.

(ii) Learned State Counsel has drawn attention towards the table given in the reply of the respondents regarding the results of the government analyst so as to contend that all the samples were of therapeutic doses. The formulations labeled in the samples as capsules, syrups, suspensions, drops and powders are the specified dosages forms in the Indian Pharmacopoeia, which is a standard for the drugs and that dosage slips are not applicable in case of dietary/ food supplements/ nutrients.

(iii) Learned State Counsel further submits that Schedule K in class of drugs at Sr. No.10 prescribes articles of foods fortified with vitamins and minerals exempted from the provisions of the Chapter IV of the Act but in the present case, no drug was having any food substance in the formulation and the ingredients were purely of Pharmacopoeia drugs and that the formulations made thereof have been duly explained against each sample.

(iv) Learned State counsel has further justified non-compliance of Section 25(3) & 25 (4) of the Act by submitting that as all the samples were declared to be of standard quality, so there was no occasion to challenge the report or re-test the drug samples from the Central Drug Laboratory and so,

Section 25(3) and Section 25(4) are not applicable and as such, there is no violation.

With these submissions, prayer is made for dismissal of the complaint.

6. I have heard the submissions of both the sides and have perused the record.

7. Annexure P.3 is the complaint filed by respondent- State against the petitioners, as per which the accused were found manufacturing allopathic drugs without having any valid drug licence in this regard. Nine samples were taken vide SD-A-26/09 to SD-A-34/09, out of which six samples were taken from finished goods and three from raw material. As per the complaint, handwritten statement was made by Harpreet Singh, partners of the firm to the effect that they do not have any manufacturing drug licence and that the name 'Abdiel Pharmaceuticals' was written due to mistake. He had produced certified copy of the Food License and some certified copies of sale record. In the complaint, details have further been given regarding the test reports of different samples received by the complainant from time to time from Government Analyst, Haryana, Chandigarh. It is also the case of the complainant that on 22.10.2009, i.e., the date of taking samples itself, a show cause notice was given to the accused and reply thereof dated 11.11.2009 was received by the complainant on 16.11.2009.

8. With the help of a table, as mentioned in reply to the petition, learned State Counsel has given details of the sample of the drugs taken, with further details regarding date of manufacture, date of expiry, report of the government analyst, ingredients found therein, as to what was the quantity in the label claimed and what was found in the drug as per

government analyst, besides the explanation on the part of the State. The said table reads as under: -

S. N.	**Sample No.**	**Name of the Drug**	**Mft. Dt./ Exp. Dt.**	**Report of Govt. Analyst**	**Ingre-dients &**	**Qty. Label Claimed/ Qty. in the Drugs as per Govt. Analyst**	**Limits as per Sche-dule `V'**	**Explanation**
1.	SD-A-26/09	**Arobion Forte Cap.**	10/2009 18 Months from the date of manufa-cturing	Standard	Vitamin B1 Vitamin B2 Vitamin B6	5mg/ 4.8 mg 5mg/ 4.9 mg 2mg/ 1.92 mg	4.5-10 mg 5-10 mg 1.5-3 mg	Therapeutic dose Therapeutic dose Therapeutic dose
2.	SD-A-27/09	**Mycibin Capsule**	08/2009 01/2011	Standard	Vitamin B1 Vitamin E	5mg/ 4.7 mg 25 mg/ 24 mg	4.5-10 mg 15-25 IU mg	Therapeutic dose Therapeutic dose
3.	SD-A-28/09	**Bevim-Forte Capsule**	10/2009 18 Months from the date of manufa-cturing	Standard	Vitamin A Vitamin B1 Vitamin B2 Vitamin B6 Niacinami de	5000 IU/ 4800 IU 10 mg/ 9.6 mg 10.0 mg/ 9.65 mg 3.0 mg/2.8 mg 50 mg/ 48 mg	5000-10000 IU 4.5-10.0 mg 5-10.0 mg 1.5-3.0mg 45-100 mg	Therapeutic dose Therapeutic dose Therapeutic dose Therapeutic dose
4.	SD-A-30/09	**Fer-CZ 200 ml Syrup**	08/2009 Best before 18 months from the date of manufa-cturing	Standard	Iron (III) Hydroxide Zinc Sulphate	150 mg/ 146 mg 10.0 mg/ 9.06 mg	--	Both the ingredients are in the contents as per the limits in the Indian Pharmacopoeia. <u>The preparation is syrup which is a defined dosage form (formulation) as per Indian Pharmacopoeia)</u>
5.	SD-A-31/09	**Abical-Z Suspensio n**	05/09 Best before 18	Standard	Elemental Calcium Vitamin	250 mg/240.5 mg 125 mg	--	Both the ingredients are in the contents as per the limits

			Months from the date of manufacturing		D3	Present		in the Indian Pharmacopoeia. The preparation is Suspension which is a defined dosage form (formulation) as per Indian Pharmacopoeia)
6.	SD-A-32/09	**Chloroform Spirit IP 66**	06/2009 3 years from the date of manufacturing	Standard	Alcohol	-	-	The product is Pharmacopeial to be used in manufacturing or sale as per due drug licenses. This is being used in manufacturing without licenses.
7.	SD-A-33/09	**Vitamin A Concentrate Powder IP 50,0000 IU/gm**	04/2009 03/2012	Standard	Vitamin A	-	-	The product is Pharmacopeial to be used in manufacturing or sale as per due drug licenses. This is being used in manufacturing without licenses
8.	SD-A-29/09	**Igovit Drops 30 ML**	09/2009 02/2011	Standard	Vitamin A	2500 IU/ 2434.98 IU	1500-5000 for children above one year up to adults	Therapeutic dose. The formulation is a drop which is a defined dosage form for pediatric use
9.	SD-A-34/09	**Ferrous Fumerate IP powder**	02/2009 01/2014	Standard	Ferrous Fumerate	-	-	The product is Pharmacopeial to be used in manufacturing or sale as per due drug licenses. This is being used in manufacturing without licenses

9. As is evident from the complaint Annexure P.3 and the reply of the respondents, though nine samples of different products were taken by the competent authority but petitioners have given details of only five samples to have been seized from their premises, without making mention of the

other four. Samples as referred by the petitioners are: (i) AROBION FORTE CAPSULE, (ii) MYCIBIN CAPSULE, (iii) BEVIM-FORTE CAPSULE (iv) FER-CZ 200 ML SYRUP and (v) ABICAL-Z 200 ML SUSPENSION i.e. products as mentioned at Sr. N: 1 to 5 in the above table. Thus, petitioners tried to conceal from the Court the samples of Chloroform Spirit, Vitamin A Concentrate Powder, Ignovit Drops and Ferrous Fumerate IP Powder, as mentioned at Sr. No.6 to 9 of the table, which were also seized from the premises of the petitioners.

10. Petitioners have alleged that the products, samples of which were taken by the complainant, are the food supplements and so, these are exempted under Rule 123 to be read with Schedule K of the Drugs and Cosmetics Rules, 1945.

11. Rule 123 of the Drugs and Cosmetics Rules, 1945 read as under: -

> *"the drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and rules made thereunder to the extent and subject to the conditions specified in that Schedule."*

12. Chapter IV of the Act, as referred in the aforesaid Rule 123, deals with the manufacturer, sale and description of Drugs and Cosmetics.

13. The relevant portion of Schedule K of the Rules, 1945 read as under: -

Class of Drugs	***Extent and conditions of exemptions.***
1. Drugs falling under clause(b) (i) of Section 3 of the Drugs and Cosmetics Act, not intended for medicinal use.	*All the provisions of Chapter IV of the Act and the rules thereunder, subject to the conditions that the drug is not sold for medicinal use or for use in the manufacture of medicines and that each container is labeled conspicuously with the words "NOT FOR MEDICINAL USE".*
Xxx	*Xxx*
9. Magnesium Sulphate	*The provisions of sub clause (i) of clause (ii)*

	of section 18 of the Act to the following extent:- *Chlorides present in the salt shall not exceed 0.12 percent in the case of the produce prepared from sea water.*
*10. The following substances which are **used both as articles as food as well as drugs**:* *(i) All the condensed or powdered milk whether pure, skimmed or malted, **fortified with vitamins and minerals or otherwise.*** *xxxxxxxxxxxxxxxxxxx*	*All the provisions of Chapter VI of the Act and rules thereunder*

14. Petitioners have relied upon Item No.10 of the Schedule K to contend that the products, samples of which were taken, were articles of food and that even if they are used in drugs also, they are exempted. However, learned State Counsel has rightly argued that as per Item No.10 reproduced above, it is only the condensed or powdered milk, whether pure, skimmed or malted, which when fortified with vitamins and minerals or otherwise, will be considered as article of food as well as drugs. In other words, if the condensed or powdered milk, whether pure, skimmed or malted, is not fortified with vitamins and minerals or otherwise, then it will not be considered as article of food as well as drugs, so as to fall in the exemption Rule 123.

15. However, in the present case, no drug is having any food substance in the formulation. Rather, as per the complaint and the report of Government Analyst, the ingredients are purely of pharmacopoeial drugs and the formulations made thereunder, as has been explained against each sample in the table given above.

16. In the afore-said circumstances, prima-facie petitioners cannot be allowed to seek exemption under Rule 123 to be read with Schedule K of the Drugs and Cosmetics Rules, 1945.

17. Petitioners also allege violation of Section 25 of the Act. The said provision reads as under: -

> ***"25 Reports of Government Analysts***. —(1) *The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.*
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> (2) *The Inspector on receipt thereof* ***shall deliver one copy of the report to the person from whom the sample was taken*** *and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.*
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> (3) *Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive* ***unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.***
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> (4) *Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the* ***Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory*** *the result thereof, and such report shall be conclusive evidence of the facts stated therein.*
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> (5) *The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct."*

18. The contention of learned counsel for the petitioners is that after receipt of the report from the government analyst in respect of samples seized from the premises of the petitioners, copy thereof was not sent to the petitioners as required under Section 25(2) of the Act, due to which

petitioners could not avail their right to challenge the said report within 28 days of the receipt of the report as per Section 25(3) of the Act. So much so, the Court concerned did not exercise its power under Section 25(4) of the Act to send the sample to the Central Food Laboratory for testing. Attention is further drawn that when the complaint was filed on 10.03.2012, the shelf life of the samples had expired.

19. It has already been noticed that the petitioners have given reference of only five samples in this petition and not of all the nine. No doubt, that shelf life of five of the products as referred by the petitioners i.e. that of Arobion Forte Cap, Bevim-Forte Capsule, Mycibin Capsule, Fer-CZ 200 ml Syrup and Abical-Z-Suspension, as mentioned at Sr. Nos.1 to 5 of the table forming part of the reply of the respondents, had expired when the complaint was filed on 10.03.2012, but the said shelf life had not expired in respect of samples of four other products mentioned at Sr. No.6 to 9.

20. Apart from above, it is not in dispute that on analysis, samples of all the nine products, were found to be of standard quality, as is evident from the reports of the government analyst available on record and as also mentioned in table forming part of the reply. It is in the light of this fact that all the samples were found to be of standard quality that it is contended by learned state counsel that there is no violation of Section 25, inasmuch as there was no occasion for re-testing of the samples. The allegation against the petitioners is that they were manufacturing the products despite these being drugs, without holding the drug licence.

21. There appears to be merit in the afore-said contention. No doubt that the accused has right under Section 25(2) of the Act to be notified in writing of the report signed by the government analyst, so that within 28 days of the receipt of the report, as per Section 25 (3), he can notify his

intention to the Inspector or the Court concerned to adduce evidence to controvert the report. Similarly, under Section 25 (4), the intention to be notified for re-testing through the Central Food Laboratory is for adducing evidence in contravention of the Government analyst report. However, the words "in contravention of the report" as used in sub-section (3) and sub-section (4) of Section 25 are significant, as they indicate the legislative intent and the objective of the provision, so as to provide an opportunity to the accused to get the sample re-tested from the Central Food Laboratory for the purpose of controverting the report of the government analyst.

22. However, in the present case, samples of all the nine products, were found to be of standard quality and so, there was no occasion for controverting the report of the government analyst. The accused were required to produce the licence so as to manufacture the drugs.

23. Thus, the only question to be considered by the Court is as to whether the products, samples of which were drawn, were drugs within the meaning of Section 3(b) of the Act, as is alleged by the respondent State; or the same are foods/ dietary supplements, as is claimed by the petitioners - accused. Prima-facie, case of the petitioners does not fall under Rule 123 to be read with Schedule K of the Rules, as has been stated earlier and so, in these circumstances, no rights of the petitioners- accused have been violated under Section 25 of the Act.

24. As far as ***Medicamen Biotech Ltd.'s case (supra)***, relied upon learned counsel for the petitioners is concerned, in that case, sample of drug was declared by the government analyst to be sub-standard and it was in these circumstances that it was held that accused were deprived of a valuable right under Section 25(3) and 25(4) of the Act, as challan was put up in the Court about a month short of expiry date of the shelf life of the drugs.

Similar was the situation in ***Balwinderjit Singh's case (supra),*** as in that case also, petitioners could not avail their legal right to get the sample re-tested from the Central Food Drugs Laboratory, as initially the sample analysed by the government analyst, was found to be spurious. As such, both the cited authorities are distinguishable on facts and so, of no help to advance the case of petitioners because in the present case, all the samples were found to be of a standard quality.

25. Consequently, this Court finds no merit in the present petition. The same is hereby dismissed.

September 29, 2023 **(DEEPAK GUPTA)**
renu **JUDGE**

Whether Speaking/reasoned Yes/No
Whether Reportable Yes/No