

IN THE HIGH COURT OF JUDICATURE AT PATNA
Civil Writ Jurisdiction Case No.22940 of 2019

Hindustan Medicine Private Limited P.O.- Barauni, P.S.- Phulwaria, District- Begusarai- 851 112 engaged in Manufacturing, Sale and Distribution of Drugs specified in Scheduled- C and C1 and being represented through its Authorized Signatory, Sri Ravish Kumar, aged about- 42 years, Male, S/o Sri Yogendra Mandal, resident of Paramhans School Campus, Sanskar Vatika Road, Nr. Durgamandir Asthan, Mungeriganj, P.S.- Town, Begusarai.

... .. Petitioner/s

Versus

1. The State of Bihar through the Principal Secretary-cum- Appellate Authority, Department of Health and Family Welfare, Government of Bihar, Patna.
2. The Principal Secretary-cum- Appellate Authority, Department of Health and Family Welfare, Government of Bihar, Patna.
3. The State Durg Controller, Directorate of Health Services, Bihar, Patna.
4. The Durg Inspector, Begusarai- 2, Drugs Control Administration, Begusarai.
5. The Drug Inspector, CDSCO (EZ), Kolkata

... .. Respondent/s

Appearance :

For the Petitioner/s : Mr. Avinash Kumar, Adv.
For the Respondent/s : Mr. Binod Kr. Yadav (Sc18)

CORAM: HONOURABLE MR. JUSTICE A. ABHISHEK REDDY
ORAL JUDGMENT

Date : 06-02-2024

Heard the learned counsel for the parties.

2. This writ petition has been filed for the following relief(s):-

“i. For issuance of appropriate Writ in the nature of Certiorari to quash the order contained in Letter No.-1358 dated 18.10.2019 passed by the Principal Secretary-cum-Appellate Authority, Department of Health and Family Welfare, Government of Bihar, Patna in Appeal No.-15/2019 affirming the order of In-charge State



Drug Controller, Directorate of Health Services, Bihar, Patna contained in Memo no.-429(15) dated 24.04.2019 by which the manufacturing License of the petitioner being License no.-BR-76(N)AL/14 has been cancelled from the date of receipt of the letter and further in consequence there upon to quash the order contained in memo no.-429(15) dated 24.04.2019 which has been affirmed in the aforesaid Appeal de-hors the statutory provisions beside the impugned order being perverse, illegal and without jurisdiction.

ii. For further indulgence of this Hon'ble Court to stay the operation of the impugned order of cancellation during pendency of the present writ application taking into account that the products so prohibited have shelf life and would get expired resulting into huge loss to the Petitioner Company without those products having been tested to the touch stone of statutory provision for classifying those products to be not of prescribed standard."

3. Learned counsel for the petitioner has stated that the petitioner is a manufacturing unit and that his license is valid till 28.01.2029. Learned counsel has stated that the authority concerned has passed the impugned order in violation of the provisions of the Drugs and Cosmetics Act, 1940, more particularly Section 23(3), 23(4), 25(3) and 18(A), and also the rules framed thereunder. Learned counsel has stated that the



authority did not follow the procedure contemplated under the Act and has collected the samples from the drug store, Government Hospital, Gaya. That, as per the procedure contemplated under Section 23(3) and 23(4), the authorities have to take four samples and while sending the same to different laboratories have to send one sample to the manufacturer i.e. the petitioner. But the authorities, in violation of the same, have not sent any sample to the petitioner herein. Learned counsel has stated that the right of the petitioner to challenge the test report of the authorities stood defeated as the sample as mandated under the Act has not being sent to the petitioner. Though, the petitioner had made a requisition to the authorities concerned for sending the sample, the same has been rejected by the authority concerned. Learned counsel has stated that the impugned order is passed without considering the request of the petitioner to give him a sample so as to challenge the test report relied by the authorities. Learned counsel has stated that though the petitioner has taken the above mentioned grounds in the memo of appeal filed by the petitioner, the same has not been considered by the appellate authority. Further, the learned counsel has stated that the authority which has passed the order that is not competent to pass the said order as he does not have any authorization under Rules 59(1) and 67(A)(I) of the rules. Learned



counsel has stated that, as per Rule 2B, it is only the Central License Approving authority which is competent to pass necessary orders and not the State Government. That the petitioner is a manufacturer and it is only the Central Licensing Authority which can pass the necessary orders and not any State Government Authority. Learned counsel for the petitioner has relied on the judgment of the Hon'ble Supreme Court of India in Criminal Appeal No. 364 of 2017 to buttress his contention.

4. Per contra, learned counsel appearing on behalf of the State-Respondents has vehemently opposed the very maintainability of the present writ petition and has stated that the impugned orders passed by both the appellate as well as the primary authority are in consonance with the well established principles of law, the provisions of the Act and the Rules framed thereunder. Learned counsel has stated that the inspection was done in the premises of the petitioner, therefore, the contention of the petitioner that the samples were taken from the drug store at Government Hospital, Gaya is factually incorrect. Learned counsel has stated that based on the recommendations made by the Central Authority concerned i.e. Assistant Controller (India), the authorities have conducted a joint inspection of the premises of the petitioner and thereafter, based on the investigation report dated



29.01.2019, the authorities have taken necessary action. Learned counsel has, therefore, prayed this Hon'ble Court to dismiss the present writ petition.

5. In order to appreciate the issue involved in the present writ petition, it is pertinent to extract the relevant provisions of the Drugs and Cosmetic Act, 1940 and also the relevant **Sections i.e. 18(A), 23(3), 23(4), 25(3), and Rules 68, 68A and Rule 85 of the Drugs Rules, 1945:-**

“Section 18-A. 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.

Section 23(3). Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug [or cosmetic] is



being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

Section 23(4) *The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—*

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug [or cosmetic]; and

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

Section 25(3) *Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to 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.

Rule 68. *Manufacture on more than one set of premises.-- If drugs are manufactured on more than one set of premises a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.*

Rule 68-A. *Grant [***] of Licences by the Central Licence Approving Authority.— (1) Notwithstanding anything contained in this Part, on and from the commencement of the Drugs and Cosmetics (Amendment) Rules, 1992, a licence for the manufacture for sale or distribution of drugs as specified from time to time by the Central Government by notification in the Official Gazette, for the purpose of this rule, shall be [***] by the Central Licence Approving Authority (appointed by the Central Government):*

*Provided that the application for the grant [***] of such licence shall be made to the Licensing Authority.*

*(2) On receipt of the application for grant [***] of a licence, the licensing authority shall,-*

(i) verify the statement made in the application form;



(ii) cause the manufacturing and testing establishment to be inspected in accordance with the provisions of rule 79; and

(iii) in case the application is for the renewal of licence, call for the information(s) of the past performance of the licensee.

(3) If the licensing authority is satisfied that the applicant is in a position to fulfil the requirements laid down as in these Rules, he shall prepare a report to that effect and forward it along with the application 3 [and the licence (in triplicate) to be granted [***], duly completed] to the Central Licence Approving Authority:

Provided that if the licensing authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these Rules, he may, by order, for reasons to be recorded in writing, refuse to grant [***] the licence, as the case may be.

(4) If on receipt of the application and the report of the licensing authority referred to in sub-rule (3) and after taking such measures including inspection of the premises by the Inspector, appointed by the Central Government under section 21 of the Act, with or without an expert in the concerned field if deemed necessary, the Central Licence Approving Authority, is satisfied that the applicant is in a position to fulfil the requirements laid down in these Rules, he may grant [***] the license, as the case may be:

Provided that if the Central Licence Approving Authority is of the opinion that the



applicant is not in a position to fulfil the requirements laid down in these rules, he may, notwithstanding the report of the licensing authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of licence, as the case may be.

Rule 85.*Cancellation and suspension of licences. - (1) The Central Licence Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates [or direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.*

*(2) The Licensing Authority may, for such licences granted [***] by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, [or direct the licensee to stop manufacture, sale or distribution of the said drugs*



and [thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector] if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.

(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licensing Authority under sub-rule (1) or sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.”

6. A perusal of the above Sections of the Drugs and Cosmetics Act, 1940 and the rules framed thereunder clearly mandate that the Central Government is having the necessary powers to pass any orders for cancellation of the license of the manufacturer in case of any of the violation of the provisions of the Act or the rules framed thereunder. The above provisions clearly define the procedure which has to be followed by the authority concerned while taking the samples. Sections 23(4) and 25 clearly mandate that while taking the samples from the premises of a retailer, the same has to be divided into four portions



and one portion is required to be sent to the manufacturer of the particular drug. However, in this case the same has not been done by the authority concerned. The Hon'ble Supreme Court in Criminal Appeal No. 364 of 2017 has held as under:-

“6. A reading of the provisions of Sections 23(4) and 25 of the Act would indicate that in the present case the sample having been taken from the premises of the retailer had to be divided into four portions; one portion is required to be given to the retailer; one portion is required to be sent to the Government Analyst and one to the Court and the last one to the manufacturer whose name, particulars, etc. is disclosed Under Section 18A of the Act. In the present case, admittedly, one part of the sample that was required to be sent to the Appellant (manufacturer) Under Section 23(4)(iii) of the Act was not sent. Instead, what was sent on 22nd March, 2012 was only the report of the Government Analyst. When the part of the sample was not sent to the manufacturer, the manufacturer could not have got the same analyzed even if he wanted to do so and, therefore, it was not in a position to contest the findings of the Government Analyst. In the present case, the sample was sent to the Appellant-manufacturer on 10th August, 2012 and on 13th September, 2012 the Appellant had indicated its desire to have another part of the sample sent to the Central Laboratory for re-



analysis. This was refused on the ground that the aforesaid request was made much after the stipulated period of 28 days provided for in Section 25(3) of the Act.

8. All the aforesaid facts would go to show that the valuable right of the Appellant to have the sample analyzed in the Central Laboratory has been denied by a series of defaults committed by the prosecution; firstly, in not sending to the Appellant- manufacturer part of the sample as required Under Section 23(4)(iii) of the Act; and secondly, on the part of the Court in taking cognizance of the complaint on 4th March, 2015 though the same was filed on 28th November, 2012. the delay on both counts is not attributable to the Appellants and, therefore, the consequences thereof cannot work adversely to the interest of the Appellants. As the valuable right of the accused for re-analysis vested under the Act appears to have been violated and having regard to the possible shelf life of the drag we are of the view that as on the date the prosecution, if allowed to continue, would be a lame prosecution.”

7. Admittedly, in this particular case, the first sample was taken from the Drug Store situated at Government Hospital, Gaya and not from the premises of the petitioner, the same is clearly evident from the show cause notice issued to the petitioner on 09.10.2018. Further, it is also pertinent to note that though the samples were taken by the authority concerned, the sample has not



been given to the manufacturer so as to enable him to challenge the test report and the same is in violation of Section 23(4)(iii). The provisions of the Drugs and Cosmetic Act clearly mandate that insofar as manufacturers are concerned, it is only the Central Government which is having the necessary power to pass any orders either for revoking, or cancelling or suspending the license issued. In this case the impugned order has been passed by the State Government and not by the Central Government which is also in violation of the above mentioned provisions of the Drugs and Cosmetic Act, 1940 and the rules framed thereunder.

8. Though the counsel for the respondents has tried to impress upon this Court that the order has been passed based on the second inspection report which was conducted at the behest of the Central Authority, it is pertinent to note that absolutely no show cause notice was issued to the petitioner before passing the impugned order of cancellation. If the respondents are relying on the second report, the minimum that was expected from them was to issue a show cause notice to the petitioner but the same is absent in this particular case. The impugned order of cancellation is passed on the basis of the first show cause notice and also the first test report and not on the basis of the second test report which is in violation of the provisions of the Act and the Rules framed



thereunder. If it is passed on the second test report then the same is done in violation of principles of natural justice and equity as the petitioner was neither given any show cause notice of any explanation was sought before the impugned order is passed. The principles of natural justice and equity mandate that a person given an opportunity of filing his explanation against any allegations made. The order can be passed only after issuing a show cause notice, but in this particular case, the authorities did not give the petitioner show cause notice after the second test report was obtained. Moreover, as already held above, the State Government did not have the power or jurisdiction to pass the impugned order of cancellation. The order impugned in the present writ petition has also to be held bad as the same is in violation of the provisions of the Act, more particularly Section 23(4)(iii).

9. Further, it is well settled proposition of law that when a particular thing is to be done in a particular manner the same has to be done in the very particular manner and not otherwise. If any order is passed contrary to the same, then it has to be necessarily held to be bad and *non est* in the eye of law. The Hon'ble Supreme Court in ***Tata Chemicals Ltd. v. Commissioner of Customs (Preventive), Jamnagar*** has held as under:-

“18. The Tribunal's judgment has proceeded on the basis that even though the



samples were drawn contrary to law, the appellants would be estopped because their representative was present when the samples were drawn and they did not object immediately. This is a completely perverse finding both on fact and law. On fact, it has been more than amply proved that no representative of the appellant was, in fact, present at the time the Customs Inspector took the samples. Shri K.M. Jani who was allegedly present not only stated that he did not represent the clearing agent of the appellants in that he was not their employee but also stated that he was not present when the samples were taken. In fact, therefore, there was no representative of the appellants when the samples were taken. In law equally the Tribunal ought to have realised that there can be no estoppel against law. If the law requires that something be done in a particular manner, it must be done in that manner, and if not done in that manner has no existence in the eye of the law at all. The Customs Authorities are not absolved from following the law depending upon the acts of a particular assessee. Something that is illegal cannot convert itself into something legal by the act of a third person.”

10. The above stated principle has been rejected by the Hon’ble Supreme court in ***Babu Verghese v. Bar Council of Kerala, Rao Shiv Bahadur Singh v. State of Vindhya Pradesh,***



1954 reported in 1954 SCR 1098 and State of Uttar Pradesh v. Singhara Singh, AIR 1964 SC 358 has held as under:-

“27. Then it is to be seen that the Act requires the Board to exercise the power under Section 119 in a particular manner i.e. by way of issuance of orders, instructions and directions. These orders, instructions and direction are meant to be issued to other income-tax authorities for proper administration of the Act, the Commission while exercising its quasi-judicial power of issuing directions to other income-tax authorities. It is normal rule of construction that when a statute vests certain owner in an authority to be exercised in a particular manner then the said authority has to exercise it only in the manner provided in the statute itself. If that be so since the Commission cannot exercise the power of relaxation found in Section 119(2)(a) in the manner provided therein it cannot invoke that power under Section 119(2)(a) to exercise the same in its judicial proceedings by following a procedure contrary to that provided in sub-section (2) of Section 119.”

11. Having regard to the judgment of Hon’ble Supreme Court passed in Criminal Appeal No. 364 of 2017, the impugned order of cancellation and also the order of the appellate authority has to be necessarily set aside.

12. In view of the above facts and circumstances, the impugned order passed by the Primary authority, In-charge State



Drug Controller, Directorate of Health Services, Bihar, Patna dated 24.04.2019 as well as the appellate order dated 18.10.2019 passed by the Principal Secretary-cum-Appellate Authority are hereby set aside and the present writ petition is accordingly allowed however without costs.

(A. Abhishek Reddy , J)

Gauravkr/-

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