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IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CIVIL APPELLATE JURISDICTION

WRIT PETITION NO. 5586 OF 2015

M/s. Raj Pharma

Shop No.16-21, Anand Bhauvan,
Babu Genu Road, Mumbai – 400 002.

Through its Partner

Shri. Niren M. Shah

Age : 41 years, Occ.: Business

Having the above business address.

.. Petitioner

Versus

1. State of Maharashtra,

Through its Ministry of State for
Food and Drug Administration Department,
Maharashtra State, Mantralaya at Mumbai.

2. Assistant Commissioner,

(Zone 1) & Licensing Authority
Food and Drug Administration Department,
Maharashtra State, at Brahanmumbai.

.. Respondents

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- Mr. Manoj A. Patil for Petitioner.
- Ms. V.S.Nimbalkar, AGP for the Respondent- State.

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CORAM : MILIND N. JADHAV, J.

RESERVED ON : JULY 29, 2022

PRONOUNCED ON : OCTOBER 06, 2022.

JUDGMENT :

1. Rule. Rule made returnable forthwith.

2. By the present Writ Petition, Petitioner has challenged legality and validity of order dated 12.06.2015 passed by the Hon'ble Minister of State for Drugs and Cosmetics Department, Maharashtra State in statutory Appeal No.2014/Pro.No.102/Shikana-156(15)

/Drugs-2 filed under the provisions of Rule 66(2) read with Rule 67-H(2) of the Drugs and Cosmetics Act, 1940 (for short “**the said Act**”) and the Drugs and Cosmetics Rules, 1945 (for short “**the said Rules**”) framed thereunder. By order dated 28.11.2014, Respondent No.2, Licensing Authority directed suspension of license issued under the said Act of Petitioner for a period of 60 days. By the impugned order, Respondent No.1, Appellate Authority reduced the sentence from 60 days to 10 days and directed enforcement of suspension from 25.06.2015 to 04.07.2015. Being aggrieved, the Petitioner filed the present Writ Petition challenging the impugned orders.

3. On 24.06.2015, this Court passed ad-interim order of stay of impugned order. Writ Petition was listed for admission on 29.07.2022 when by consent of both parties it was heard finally.

4. Facts which emerge for consideration for adjudication in the present case are as follows:-

4.1. Petitioner (M/s. Raj Pharma), a partnership firm, holds a valid license being License No.MZ-1/M2/893 (License No.20-B), MZ-1/M2/887 (License No.21-B) issued under the said Act and the said Rules framed thereunder. It runs a pharmaceutical shop in Mumbai. There is no dispute about the license.

4.2. On 11.07.2014, Respondent No.2 (Assistant Commissioner, (Zone 1) & Licensing Authority) conducted inspection of Petitioner's

premises and found the following violations:

- (i) that Petitioner was selling drugs over the counter;
- (ii) that Petitioner did not sell drugs to the authorized person;
- (iii) that details of drugs provided to Doctors between 01.04.2014 to 30.06.2014 were not made available; and
- (iv) that Petitioner did not produce the pricelist of drugs.

4.3. Above violations were notified in inspection report dated 11.07.2014.

4.4. Show cause notice dated 19.07.2014 was issued under Rules 61(1) and 67-H calling for explanation from Petitioner as to why its license should not be suspended/cancelled for the violations.

4.5. On 25.07.2014, Petitioner filed reply to show cause notice and furnished detailed explanation alongwith documents. It was contended that there was no violation of Rules and Petitioner produced the entire details sought for by Respondent No.2.

4.6. On 28.11.2014, Respondent No.2 passed order holding that since Petitioner did not comply with the mandatory Rules in the course of conducting its pharmaceutical business and therefore in exercise of powers under Rule 66(1) license of the Petitioner's

premises stood suspended for a period of 60 days beginning from 29.12.2014 to 26.02.2015.

4.7. Being aggrieved, Petitioner preferred statutory Appeal under Section 66(2) of the Rules before Respondent No.1.

4.8. Initially Respondent No.1 by order dated 23.12.2014 granted interim stay to the impugned order. Hearing was conducted on 26.02.2015 and after hearing Petitioner impugned order dated 12.06.2015 came to be passed directly suspension of Petitioner's license for 60 days to 10 days, *inter alia*, holding that it was in the interest of the public at large and for the safety of the public.

5. I have heard Mr. Manoj Patil, learned Advocate appearing for Petitioner and Ms. V.S. Nimbalkar, learned AGP appearing for Respondents and with their able assistance perused the record of the case.

6. Mr. Manoj Patil submitted that the impugned order is unsustainable since Petitioner had produced the entire details sought for by Respondent No.2 vide the show cause notice, as also by Respondent No.1 during the hearing of statutory Appeal. He submitted that the order dated 28.11.2014 passed by Respondent No.2 itself records that Petitioner has produced entire details. He submitted that on consideration of the factual material produced by Petitioner, it was incumbent upon Respondent No.2 initially as well as Respondent No.1

subsequently to consider the material produced and pass appropriate orders. Rather the authorities did not consider or discuss the material and explanation provided by Petitioner and passed the orders for suspension merely on extraneous grounds which are not germane to facts and circumstances of the present case. He submitted that suspending/cancelling of license, albeit for a short duration, is a very harsh penalty which has been passed without considering and appreciating the explanation given by Petitioner and hence the impugned order deserves to be set aside. He submitted that in the order dated 28.11.2014 passed by Respondent No.2, at two places it is recorded that the intent and purport of charge Nos.1 and 3 have been accepted/admitted by Petitioner. He submitted that Petitioner has not admitted any charges/allegations in the Show Cause Notice and the same therefore needs to be seen in its proper perspective. He has carefully read the first order dated 28.11.2014 and the impugned order dated 12.06.2015 in juxtaposition with the explanation offered by Petitioner in reply to the show cause notice. He has therefore submitted that in view of the details furnished, the impugned order levying suspension of 10 days is bad in law and be set aside.

7. ***PER-CONTRA***, Ms. V.S. Nimbalkar, learned AGP appearing on behalf of Respondents has drawn my attention to the Affidavit-in-Reply dated 11.04.2016 filed by the Assistant Commissioner (Drugs),

(Zone-I), Mumbai, Licensing Authority, Foods and Drug Administration, Maharashtra State and contended that in reply to show cause notice dated 25.07.2014, explanation offered by Petitioner was found to be unsatisfactory and hence the original order came to be passed. She submitted that the impugned order in the present petition is a reasoned order passed after hearing the Petitioner. She submitted that the provisions of Rule 65 of the said Rules directly apply to the Petitioner's case since it holds a license under the said Rules in Form 20B and 21B and conditions for holding such license fall under Rule 65. Hence she has prayed for dismissal of the Petition.

8. Before I advert to consider the material furnished by Petitioner, it would be apposite to reproduce the relevant statutory provisions in respect of which the Petitioner has been indicted and punished. Rule 65 is relevant and reads thus:-

“65. Condition of licenses.

(1)

(2)

(3) (1) *The supply of any drug other than those specified in Schedule X on a prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription. The following particulars shall be entered in the register:-*

(a) serial number of the entry,

(b) the date of supply,

(c) the name and address of the prescriber,

(d) the name and address of the patient, or the name and

address of the owner of the animal if the drug supplied is for veterinary use,

(e) the name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof,

(f) in the case of a drug specified in Schedule C or Schedule H the name of the manufacturer of the drug, its batch number and the date of expiry of potency, if any,

(g) the signature of the registered Pharmacist by or under whose supervision the medicine was made up or supplied:

Provided that in the case of drugs which are not compounded in the premises and which are supplied from or in the original containers, the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose:

Provided further that if the medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion:

Provided further that it shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of—

(i) any drugs supplied against prescription under the Employees State Insurance Scheme if all the above particulars are given in that prescription, and

(ii) any drug other than that specified in Schedule C or Schedule H and Schedule H-1 if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made and on condition that the provisions of sub-rule (4)(3) of this rule are complied with.

(h) the supply of a drug specified in Schedule H-1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.

(2) The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the licensing authority at the time of application for the grant of the license to sell by retail:

Provided that the licensing authority may require records to be maintained only in prescription register if it is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible.

(4)

(5) (1) *Subject to the other provisions of these Rules the supply of a drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his license number under the Drugs and Cosmetics Act in which the following particulars shall be entered:-*

(a) the date of sale,

(b) the name, address of the licensee to whom sold and his sale license number. In case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a Registered Medical Practitioner for the purpose of supply to his patients the name and address of the authority, institution or the Registered Medical Practitioner as the case may be,

(c) the name of the drug, the quantity and the batch number,

(d) the name of the manufacturer,

(e) the signature of the competent person under whose supervision the sale was effected.

(2)

(6) *The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these Rules, and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.*

(7)

(8)

(9) (a)

(b) The supply of drugs specified in Schedule H or Schedule H-1 or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years."

9. From the record of the case it is seen that Petitioner is an old establishment and a stockiest of various medicines in Mumbai. There

are four charges levelled against Petitioner in the Show Cause Notice, viz; (i) that Petitioner was selling drugs over the counter; (ii) that Petitioner did not sell drugs to the authorized person; (iii) that details of drugs provided to Doctors between 01.04.2014 to 30.06.2014 were not made available; and (iv) that Petitioner did not produce the pricelist of drugs.

10. In this context, it would be pertinent to see the reply to the show cause notice offered by the Petitioner. In Petitioner's reply dated 25.07.2014, Petitioner has replied to the aforesaid four charges are as under:-

"With reference to the content of para 1 of the notice that I state that it is not correct that the supply was made to unknown person. The ID proof and the authority letter from the respective licensee are enclosed herewith for ready reference. The observation stated in point 1 does not lead to the violation of rule 65(5)(1). The essential constituents leading to violation of rule 65(5)(1) are missing in the allegations.

With reference to the content of para 2 of the notice I enclose herewith the copy of order from respective party. The observation stated in point 2 does not lead to the violation of rule 65(3).

With reference to the content of para 3 of the notice I explain that the medicine were supplied against the order from respective party. The copies of orders are enclosed herewith. The observation stated in point 3 does not lead to the violation of rule 65(9)(b)

With reference to the content of para 4 of the notice no manufacturer is providing pricelist to their authorized stockiest. All the content of the pricelist are now covered in the Invoice copy itself, such as MRP, PTR, PTS, Discount structure etc.

However, authorities should asked manufacturer to provide basic pricelist and copy of amendments there after to authorised stockiests as they were doing in the past."

10.1. In paragraph No.6 in the Affidavit-in-Reply which is response to paragraph No.10(d) of the petition, it is stated that Petitioner has produced the details sought however the explanation forwarded by Petitioner was found to be unsatisfactory.

11. Thus it is seen that in respect of charge/allegation No.1, Petitioner has provided identity proof and the authority letter from the respective licensee for reference to Respondent No.2. In respect of charge/allegation No.2, Petitioner has enclosed copy of orders received from the authorised persons/doctors/medical stores. In respect of charge/allegation No.3, copies of orders received from parties were furnished by Petitioner which were missing and lastly in so far as the pricelist is concerned, Petitioner has stated that no manufacturer provided pricelist to the authorized stockist and all contents of the pricelist are now covered in the invoice copy such as MRP, PTR, PTS and discount structure etc. Petitioner has urged the licensing authority to issue appropriate directions to the manufactures to issue pricelist to stockist.

12. Considering the aforementioned explanation alongwith the copies provided by Petitioner it was incumbent upon Respondent No.2, Licensing Authority to adjudicate and decide the violation. Violation of Rules 65(5)(1), 65(3), 65(9)(b) and 65(6) is alleged in the present case.

13. In this background, it is pertinent to re-visit the findings in the original order dated 28.11.2014 to see whether there is proper consideration or otherwise. In respect of the charge regarding the over counter sale of drugs, it is alleged that on 11.07.2014 there were two specific bills being Bill No. 4077 and 4076 issued to purchaser of medicines in Vapi, Nani Daman and Udvada and it is alleged that the same person had purchased the medicines by paying cash across the counter and the person who purchased the medicines was not known to the person who sold the medicines. In reply to this charge/allegation the impugned order itself states that the ID proof and authority letter alongwith explanation has been received from Petitioner at the time of hearing. Petitioner as also identified the purchasers being proprietors of M/s. Purohit Medical, Vapi; Royal Chemist, Udvada and Dreamland Medicals, Daman. It is seen that these three entities were from outside the State. Petitioner has provided all details about the three entities who purchased the medicines across the counter. Hence there cannot be any violation.

14. In so far as the charge of not providing details of sale under Rule 65(5)(1) is concerned, Respondent No.2, Licensing Authority has itself noted in its order dated 28.11.2014 that Petitioner has provided the ID proofs and authority letters alongwith his explanation. Details of the three purchasers to whom the Petitioner had sold the Scheduled

drugs across the counter have been provided; they are Purohit Medicals, Vapi and Royal Chemist, Udvada. Petitioner has provided the authority letters from two out of the three purchasers; in so far as the third purchaser is concerned, Petitioner has furnished the details of sale made to Dreamland Medicals situated at Daman. Hence the Petitioner has not suppressed any information to the knowledge of the Petitioner from the licensing authority on being called upon to do so.

15. In so far as violation of the provisions of Rule 65(3) is concerned, it is alleged that there has been dereliction of duty on the part of Petitioner to maintain the entire record as provided under the said Rule. However Petitioner has provided details of the licensee who has purchased the Scheduled drugs against the bill number and date which finds specific mention in paragraph No.2 of the original order dated 28.11.2014 passed by Respondent No.2. Petitioner has provided details of the purchasers/licensees namely; Nagri Medical and General Stores, Mumbai 17, Shri Sai Krupa Medical Stores, Umargaon (Gujarat) and Mohammedi Stores, Mumbai 9 against the respective bill numbers. *Prima facie*, Petitioner has complied with the provisions of Rule 65(3) and there seems to be no dereliction on its part whatsoever. Contention of Respondents that pursuant to sale of medicine across the counter, whether the medicine has reached the concerned licensee or otherwise cannot be within the purview ambit

and power of the Petitioner. Petitioner is a stockist and license holder and has been carrying on the trade for several years and has sold the drugs to a purchaser.

16. In respect of the charge under Rule 9(3), Petitioner is required to sell prescribed Schedule 'X' and 'H' drugs only to registered medical practitioners, hospitals, dispensaries and nursing homes on receiving signed orders in writing. Petitioner has produced on record the signed orders and requisitions made by doctors and therefore it was incumbent upon Respondent No.2 to consider the same and give a reasoned finding thereon. Despite the Petitioner providing such details to the licensing authority, the same have not been considered save and except, it is stated that Petitioner has submitted the details. Hence this charge is also not maintainable.

17. In respect of the charge under Section 65(6), Petitioner has confirmed that the invoice issued by the Petitioner contains all details of pricing of medicines as required and there is no suppression of any material fact whatsoever in respect of the requirement of this particular provision.

18. After perusal of the record and the relevant statutory provisions, I am of the opinion that Petitioner has furnished substantial details which have not been considered by Respondent No.2 Licensing Authority and which ought to have been considered before passing the

original order of suspension. The first Appellate Authority has also not considered the Petitioner's grievance in the light of the statutory provisions alluded to hereinabove and the material furnished by the Petitioner.

19. In view of the above discussion and findings, I am of the opinion that the Petitioner has made out an arguable case. It is seen that Petitioner has furnished the entire relevant information in reply to the show cause notice. Hence the original order passed by the Respondent No.2 Licensing Authority and the impugned order passed by Respondent No.1, first Appellate Authority call for interference. Both orders dated 28.11.2014 and 12.06.2015 passed by Respondent No.2 Licensing Authority and Respondent No.1 respectively stand quashed and set aside. Needless to state that the Show Cause Notice dated 19.07.2014 also stands dismissed.

20. With the above directions, Petition stands disposed. Rule is made absolute in the above terms.

[MILIND N. JADHAV, J.]

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