(2009) 09 AHC CK 0116

In the Allahabad High Court

Case No : Writ Petition No. 4115 (M/B) of 1998

New Redson Laboratory (India) — APPELLANT

Vs

State of U.P. and Others — RESPONDENT

Date of Decision : 14-09-2009

Acts Referred:
Drugs and Cosmetics Rules, 1945 — Rule 145A, 154, 157(2)(c), 160, 56

Citation : (2009) 09 AHC CK 0116

Hon'ble Judges : Sunil Ambwani, J and Dilip Gupta, J

Final Decision : Allowed

Judgement

1. Heard Shri Jitendra Narain Misra holding brief of Shri S.K. Kalia, learned counsel for the petitioner. Learned Standing Counsel appears for the respondents.

2. This writ petition is directed against the cancellation of the license given to the petitioner on Form 25D under Rule 154 of the Drugs & Cosmetic Rules, 1945 made under the Drugs & Cosmetics Act, 1940 for manufacture of Ayurvedic medicines. The order was stayed by the Court. The counter and rejoinder affidavits have been filed by the parties.

3. Brief facts giving rise to this writ petition are that a surprise inspection was caused at the manufacturing facility of the petitioner on 13.10.1998. The Minister of State Shri Ganga Bax Singh Ji; Dr. Raksha Goswami, Incharge Director, Ayurved and Unani Services Directorate, U.P. Lucknow; Shri R.P. Goswami, Joint Director, Ayurved Unani Services Directorate, U.P.; Shri Awadhesh Kumar Misra, Drug Inspector Headquarter, Ayurved Unani Services Directorate, U.P. Lucknow and Dr. R.C. Tripathi, Regional Ayurved Unani Officer, Kanpur were present at the time of inspection. The inspection report indicated that there was no board displayed outside the premises of the firm. Ms. Anuradha Vaish, engaged as technical expert of the firm was shown to be present in the attendance register but was absent. The other person Shri M.P. Shukla was also not present. There was no facility of ''yavkut'' of medicines kept in the factory and that there was no facility to disinfect the containers of the medicines in the manufacturing facility.

There was discrepancy in the stock register of the raw material and the stocks of raw material actually stored in the godown. The inspecting party took samples of medicines. The brass seals were put in the presence of Shri Radhe Lal Vaish, one of the partners of the firm. The inspecting party offerred the price of the samples to Shri Vaish but that he refused to accept it. The copy of the sample has been handed over to them. The details of the samples taken were given in Form 17 under Rule 56 and 145A to the partners of the firm.

4. A show cause notice dated 29.10.1998 was issued to the petitioner to reply within 15 days as to why the petitioner''s license No.A1104/84 for manufacturing drugs be not cancelled on the ground (1) the premises in which the medicines were being manufactured did not have sufficient arrangement for cleanliness and there was no arrangement for disinfecting and drying of the containers, in violation of Rule 157 (1) of the Drugs and Cosmetics Rules, 1945; (2) the raw material of manufacturing medicines was not properly stored and there was no arrangement to identify them. The checking report of the raw material was not shown tot he inspecting officer to verify whether the ''kachchi aushadhia'' were of requisite quality, thereby violating Rule 160 of the Drugs and Cosmetics Rules, 1945 and (3) an information was given that Km. Anuradha Vaish was engaged as technical staff in place of Vaidya Mahendra Prasad Shukla. On the documents made available at the time of inspection it was found that Km. Anuradha Vaish is a graduate in Chemistry and Botany but that her experience of manufacturing medicines was doubtful in as much as the certificate given by Shri Mahendra Prasad Shukla is dated 13th April, 1948 and in this manner the petitioner has not complied with Rule 157 (2) of the Drugs and Cosmetics Rules, 1945.

5. The petitioner submitted a reply on 11.11.1998 stating that the Regional Ayurvedic and Unani Officer did not carry out inspections on 13.10.1998. The Hon''ble Minister; officers and the Incharge Director, Education; Joint Director, Education and the Drugs Inspector had carried out the inspection along with Dr. R.C. Tripathi, Regional Ayurvedic and Unani Officer, Kanpur. AT the time of inspection no manufacturing activity was being carried out in the factory. The cleaning on account of the Deepawali festival was in progress, on account of which the goods were not properly arranged. There is sufficient arrangement of disinfection and drying in the laboratory shown in the map submitted and approved since 1984. In the year 1994 a new factory was built increasing the capacity by four times. The new premises were approved in the license on 4.12.1994. The ''kachchi aushadhia'' were kept outside the laboratory on account of cleaning for Deepawali festival. All the medicines were kept in separate containers with stickers. The inspection was not made with reference to the register of raw material. The petitioner is maintaining 10 registers in accordance with Rule 160 and that there is a register for analysis in which the entries are made after the checking of the raw materials. The petitioner had produced these three registers at the time of inspection and has thus not committed any violation of Rule 160 of the Rules. Km. Anuradha Vaish is a graduate in Chemistry and Botany. She was declared as technical staff and was approved by

the department since 1984. The year of the experience certificate was mentioned as mistake. She had completed B.Sc. In 1979 and had experience of manufacturing medicines from 1.6.1980 to 31.3.1984. The year of certificate in the certificate was wrongly mentioned as 1948. In the year 199495 the name of Vaidya Mahendra Nath Shukla was entered. The letter was received on 17.2.1994 on which an objection was made by the petitioner to enter the name of Anuradha Baish. The show cause notice did not refer to the analysis report and the samples taken by the inspecting party. The license was cancelled by order dated 27.11.1998 on the grounds that the petitioner did not give sufficient explanation for failing to show a requisite document at the time of inspection. There was no arrangement for disinfection of the containers and that approval of Km. Anuradha Vaish as authorised Vaidya was made on the basis of the document, which could not be believed. The licensing authority found that the petitioner had violated Rules 157 (1), 157 (2) and 160 of the Drugs and Cosmetics Rules, 1945. The order also observed that the reports received from the Government Analyst, Ayurved and Unani U.P. Lucknow dated 21.11.1998 shows the presence of Ethile Alcohol to be positive and that ultimately Radisson batch NO.399 and Ashok Radisson batch No.203 was not found to confirm to requisite standards. The license was thus cancelled with immediate effect. The petitioner did not avail the remedy of appeal and filed this writ petition in 1998. An interim order was passed by the Court.

6. Learned counsel for the petitioner submits that no manufacturing activity was being carried out at the time of inspection caused by the Hon''ble Minister, the Director, the Joint Director, The Regional Ayurvedic and Unani Officer and Drugs Inspector. It was very unusual for the minister to be a part of the inspecting party. The presence of the Minister at the time of inspection establishes malafides against the petitioner. Ordinarily a Minister does not inspect the factories and laboratories of Ayurvedic medicines. The presence of Incharge Director also demonstrated that the inspecting party took unusual interest in the inspections. The containers of the raw material and the medicines were properly labelled. They were taken out of the laboratory for cleaning of the premises. They were not properly arranged, as they had to be taken back to the laboratory for proper sticking. The inspecting party was shown all the 10 registers required to be maintained under the Rules as well as the manufacturing register and were given assistance for drying samples. The petitioner was not given the report of the analysis of the samples along with show cause notice and thus the petitioner was denied fair and reasonable opportunity to give reply to the allegations to explain the report.

7. It is contended that Dr. R.L. Vaish, Managing Partner of the petitioner wrote a letter on 2nd December, 1998 to the Regional Ayurvedic Unani Officer that his license has been cancelled but that copy of the report of analysis of the samples has not been served upon him upto date of writing of the letter on 2.12.1998. In the writ petition the petitioner has explained that the presence of Ethyle Alcohol is natural as the raw material used in the medicines generates Ethyle Alcohol by

itself as chemical reauctions.

8. With regard to qualifications of Km. Anuradha Vaish it is submitted that Rule 157 (2) provides for requisite qualifications for technical staff. Clause (c) provides graduation in Chemistry and Botany with atleast two years experience in manufacturing of drugs as one of the requisite qualifications for the technical staff. Km. Anuradha Vaish is a graduate in Botany and Chemistry from the University of Kanpur and was certified to have experience of four years in manufacturing drugs from 1980 to 1984. The mistake in putting the order of Vaidya Shri Mahendra Prasad Shukla, which could also be explained as the date of his certificate of registration No.11049A would not be a ground to cancel the license.

9. Learned Standing Counsel has relied upon contents of the counter affidavit of Dr. Ramesh Chandra, Regional Ayurvedic and Unani Officer, Kanpur. It is staged in para 4 of the counter that after receiving information from Hon''ble the State Minister, Medical Education, U.P. that the petitioner firm is manufacturing substandard drugs by mixing with toxic materials injurious to public health specially women the inspection was carried out by the Minister with the officers including the Director, Joint Director and Drug Inspector. The records were inspected and samples of the finished products were taken as per rules. Two sets of samples were sent to analysis and one set was handed over to the partner of the firm. The chemical analysis report was made for by the State Analysis, Lucknow on 21.11.1998 after the show cause notice dated 29.10.1998 was served upon the petitioner on 30.10.1998. Two products were found to be substandard showing the presence of Ethyle Alcohol on which it was decided to cancel the petitioner''s license.

10. It is not denied that the laboratory was under cleaning on account of the Deepawali. The containers were kept outside with proper labels and that raw material register, finished good register and manufacturing register were presented before the inspecting party. Smt. Anuradha Vaish was a graduate with Chemistry and Botany and was certified to have qualifications by Vaidya M.P. Shukla. The date of certificate was apparently wrongly written as it could not relate to the year 1948. The reference of the date could only be connected with the registration certificate of Vaidya M.P. Shukla.

11. We have considered the respective submissions and find that there is no mention of any manufacturing activity being carried out in the inspection report. The laboratory was under cleaning due to Deepawali and that containers of raw materials and finished products were taken out of the stores. The petitioner had produced all the registers and had clearly informed the inspecting party that the facility of disinfection and drying is available. The stores were disarranged on account of cleaning of the laboratory.

12. With regard to qualifications of Anuradha Vaish we find that Rule 157 (2) (c) provides for graduation with Chemistry and Botany with four years experience as

sufficient qualifications. The rules do not provide authority or person to certify the experience in manufacturing drugs. The date of the experience certificate on which the petitioner''s experience was doubted was apparently a mistake as the experience from 198084 could not be certified in the year 1948.

13. The respondents could not have relied upon the report of the Government Analyzer on the ground that the report was not given to the petitioner either along with show cause notice or before cancellation of the license. The licensing authority could not have relied upon a document to cancel the license unless the licensee was given a copy of the report and was required to give an explanation to the same.

14. The order cancelling the license therefore cannot be sustained. We do not find any merit in the objections that the petitioner should be relegated to filing an appeal. Such an objection cannot be validly taken after 11 years of filing of the writ petition. The petitioner''s license has been renewed in between from time to time and that after examining the matter on merits it would be inappropriate to relegate the petitioner to file appeal against the order cancelling the license.

15. The writ petition is allowed. The order dated 27.11.1998 cancelling the petitioner''s drug license No.104/84 for manufacturing ayurvedic drugs is set aside. There shall be no order as to costs.

