BEFORE THE EXCISE COMMISSIONER HIMACHAL PRADESH

Case No. 13/2021-22

Date of Institution: 09-12-2021

Date of Order: 09-02-2022

IN THE MATTER OF: -

Excise Commissioner Himachal Pradesh

Vs

M/s Aqua Parentral

Village Khari, Mauza Ogli, Kala Amb,

District Sirmour, Himachal Pradesh

(Licensee MD-VI)

Parties Represented by:-

- Shri Sandeep Mandyal, Law Officer (Legal Cell) for the Department.
- S/Sh. Sameer Thakur, Advocate and Tarun Srivastava, Technical Director, M/s Aqua Parentral for the noticee.

ORDER

- This order shall dispose of the proceedings initiated in pursuance to the issuance of Show Cause Notice under proviso to Sub-section 1 of Rule 54 of the Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989 (hereinafter referred to as "the Rules").
- The brief facts giving rise to the initiation of the present proceedings are that an FIR
 No. 52 of 2021 dated 02.06.2021under Sections 21, 29 read with Section 8 of

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NDPS Act and Sections 420, 467, 468,471 and 120 B of IPC has been registered against one Sh. Rakesh Kumar Goyal and his wife Ranjana Goyal, who are the licensees of firm viz. M/s Orison Pharma International at Police Station, Kala Amb Distt. Sirmour for illegally diverting commercial quantity of medicine tablets with Tramadol as the main ingredient which in fact is a prohibited substance under the Narcotics Drugs and Psychotropic Substance Act, 1985. After the registration of the FIR Sh. Rakesh Kumar Goyal and Smt. Ranjana Goyal have filed an application for grant of interim bail before the Hon'ble High Court of Himachal Pradesh. The Hon'ble Court vide its order dated 30.06.2021 was pleased to observe that the State of Himachal Pradesh being a hub of pharma, there may be a likelihood of similar lapses from other manufacturing units, wherein the substances come under the NDPS Act and therefore, directed the Office of the Ld. Advocate General to send a downloaded version of this order for information to the following Ld. Officers of the State of Himachal Pradesh: 1) the Chief Secretary, 2) Secretary Home, 3) Secretary Finance, 4) Secretary Personnel, 5) Secretary Health, 6) Secretary Excise and Taxation, 7) Secretary Law, 8) Director General of Police, 10) The Director Health, Safety and Regulation. The investigation in this FIR is stated to be still pending.

- 3. The licensee/noticee happens to be the Managing Partner/Director of M/s Orison Pharma International and was also possessing Chemist license in Form MD-VI and the said Chemist license (in Form MD-VI) has already been suspended by this office vide order dated 09.12.2021.
- 4. The Additional Commissioner, State Taxes & Excise-cum-Collector, South Zone also carried out the inspection of the above stated licensee/noticee (i.e. M/s Aqua Parentral) after the registration of above stated FIR and submitted its report vide letter No.EXN(SZ)-Inspecton-2021-22-5045-47 dated 6-12-2021. The said inspection was carried out in the presence of the licensee/notice. It is evident from the perusal of the inspection report that the licensee/noticee is also possessing another Chemist license in Form MD-VI for the manufacture of "KAMANI VIDRAVANRAS, KARPORAS AND ONTROL TABLET". This license was valid w.e.f. 01.04.2020 to 31.03.2021 for the financial year 2020-21 and the licensee/noticee applied for renewal of this license for the financial year 2021-22

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which in turn has been forwarded through proper channel to the undersigned for renewal on 29.07.2021.

- 5. The Learned Advocate for the noticee submitted that License in Form MD-VI (CHEMIST LICENSE) has rightly and legally been issued as per prescribed procedure in his favour by the Department for the manufacture of "KAMINI VIDRAVAN RAS AND ONTROL TABLET" and the same has rightly been renewed by this office for the year 2020-21 (up to 31.03.2021). He submitted that as the noticee deals in the manufacture and trade of Ayurvedic medicines and, therefore, the license granting authority in respect of Ayurvedic medicines is the Director Ayurveda and not the Drug Controller. Learned Advocate produced copy of the notification regarding the appointment of the Director Ayurveda as Licensing Authority in support of his claim.
- 6. Per contra, the Ld. Law Officer Sh. Sandeep Mandyal argued at the very outset, on behalf of the State that this notice should be treated as notice under Rule 53(2) of the Rules as the renewal application filed by the licensee/noticee is still pending and no further opportunity is required to be given to the licensee/noticee as it be treated as mere mentioning of the wrong provision of law especially when the proviso to Rule 54(1) (Revocation of license or permit) of the Rules as well as the Rule 53(2) (renewal of license) provides for giving opportunity of being heard in either of the two eventualities, mentioned in the said Rules. The Ld. Law Officer has further argued that neither any additional documents nor any additional fact is required to be produced/pleaded if the present notice is treated as notice under Rule 53(2) of the Rules and no prejudice will be caused to the licensee/notice, if the present show cause notice be treated as one under Rule 53(2) instead of proviso to Rule 54(1) of the Rules. The Law Officer has further argued that the licensee/noticee deliberately and intentionally did not point out the factum of the pendency of the renewal application of the above said MD-VI Chemist License. He further vehemently argued that the mere mentioning of the wrong provisions in the show cause notice hardly affects the merits of the case and issuance of any fresh notice under Rule 53(2) will be a futile exercise as no additional documents is required to be filed by either of the parties.

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- 7. The Ld. Law Officer has further argued that the Director Ayurveda is only, a Licensing Authority under the Drug and Cosmetics Act and the recommendation of the Drug Controller is statutorily required as per mandate of Rule 50(1) and in the absence of this recommendation, the renewal application of MD-VI Chemist License deserves to be rejected. It was further argued that since the licensee/noticee already contravened the terms and conditions of the Chemist License in Form MD-VI which was issued with regard to his another firm namely M/s Orison Pharma International and the said license has already been suspended therefore, the licensee/noticee is not at all entitled to get the renewal of the Chemist License in Form MD-VI with regard to the present firm i.e. M/s Aqua Parentral.
 - 8. I have heard both the parties and carefully gone through the record of the case. The perusal of the record shows that the Chemist License in Form MD-VI pending for renewal has earlier been issued without the recommendations of the Drug Controller. This fact is further fortified from the report of the Addl. Commissioner State Taxes & Excise-cum-Collector South Zone. As far as the contention raised by the licensee/noticee that the license issued by the Director Ayurveda is a sufficient compliance of Rule 50 (I) is concerned, the Chapter IV-A of the Drugs and Cosmetics Act deals with the provisions relating to AYURVEDIC, SIDDHA and UNANI Drugs and the Director Ayurveda is only notified as a Licensing Authority for Ayurvedic SIDDHA and UNANI Drugs under the Drugs and Cosmetics Act.
 - 9. The Rule 50 of the Rules, deals with the grant of chemist license and conditions thereof and Rule 50(1) provides as under:

"50(1) The Excise Commissioner or any other officer specifically empowered by him in this behalf, may on the recommendation of the <u>State Drug Controller</u>, Himachal Pradesh; grant a Chemist's license in Form MD-VI, to any person, on payment of a fee of rupees two hundred and subject to the conditions specified in sub-rule (2) of this rule:

Provided that no license in form MD-VI shall be granted to a person who does not hold the requisite license under the Drugs Rules, 1945, made under the Drugs Act, 1940, (XXIII of 1940):"

It is evident from the Rule 50(1) that the recommendation of the Drug Controller is mandatory and statutorily required for the grant of Chemist License in Form MD-VI and the mere possession of license issued by the Director Ayurveda-cum-Licensing Authority is the fulfillment of the requirement of the proviso only. It is

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evident from the record that the licensee/noticee is manufacturing KAMINI VIDRAVAN RAS AND KAPUR RUS which contains opium as one of the key ingredient and each 250 mg table of KAMINI VIDRAVAN RAS contains 80 mg of opium and each 125 mg tablet of KAPUR RUS contains about 18 mg of opium. Thus, it is evident from the record that the product manufactured by the licensee/noticee involves opium which is a Narcotics substance under the Narcotic Drugs and Psychotropic Substances Act, 1985.

10. Since, the licensee/noticee uses narcotics substance i.e. opium for the manufacturing of his products therefore, in my opinion the recommendations of Drug Controller is required and it is a condition precedent for issuance of Chemist License in Form MD-VI as per the mandate of Rule 50(1) of the Rules. The issuance of license by the Director Ayurveda-cum-Licensing Authority does not in any manner be construed as the fulfilliment of the requirement of Rule 50(1).

Even otherwise, it is a settled law based on a Latin maxim "Expressio unius est exclusio alterius" that if a statute provides for a thing to be done in a particular way, then it has to be done in that manner and in no other manner and following any other course in not permissible. Therefore, an application for renewal of MD-VI Chemist License cannot be entertained without the recommendation of the Drug Controller, Himachal Pradesh.

11. As far as the issuance of notice under proviso to Rule 54(1) instead of Rule 53(2) is concerned, it is crystal clear from the above said Rules that all that is required under the law is to give opportunity of being heard to the licensee/noticee before passing any order either for revocation of license or permit or for refusal to renew the license, as the case may be. Therefore, I found substance in the arguments of Ld. Law Officer that all that is required to give opportunity of being heard to the licensee/noticee and mere mentioning of the wrong provisions hardly affects the merits of the case and issuance of any fresh notice under Rule 53(2) will be a futile exercise as no additional documents is required to be filed by either of the parties. Even, the noticee/licensee argued the case at length though, the licensee/noticee did not point out the factum of the pendency of the renewal application during the course of hearing. Therefore, I am of the considered view that no prejudice will be

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- caused to the licensee/noticee if the show cause notice be treated one under Rule 53(2) especially when the licencee/notice knew his case from its intiation.
- 12. It is also evident from the record that an FIR has already been registered against the licensee/noticee and the Chemist License in Form MD-VI issued in his favour in respect of M/s Orison Pharma International has already been suspended. The investigation against the licensee/noticee is still going on. The registration of an FIR against the noticee/license itself shows that the licensee/noticee violated the terms and conditions of the license. Furthermore, it is evident from the inspection report that the M/s Aqua Parentral is sharing its same administrative office along with M/s Orison Pharma and M/s R.R Biotech(P) Ltd. Since, the FIR has already been registered against the licensee/noticee and investigation is already pending and the Chemist License in Form MD-VI issued in favour of the licensee/noticee in respect of M/s Orison Pharma International already stood suspended therefore, I found no reasons to renew the present MD-VI License as the present proceedings in my considered opinion are to be decided on the basis of preponderance of probabilities rather than on the basis of proof beyond all reasonable doubt.
- 13. Keeping in view the discussion made hereinabove, in my opinion the renewal application of the licensee/noticee is liable to be refused and is refused accordingly with a liberty reserved to the licensee/noticee to submit the renewal application if so desires, alongwith the recommendation of the Drug Controller as per mandate of Rule 50(1), provided the licensee/noticee fulfils the other requirements of law required for applying of such license.

14. Inform all the concerned.

15. File after completion be consigned to records. Record requisitioned from other authorities be returned, respectively.

Announce on this 9th Day of February, 2022.

Excise Commissioner, Himachal Pradesh

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Endst. No. Do ST&E/EC-Reader/2021-22/3595-3601

Dated: 10-02-2022

Shimla-171009

Copy for information to:

- M/s Aqua Parentral, Village Khari, Mauza Ogli, Kala Amb, District Sirmour, Himachal Pradesh (Licensee MD-VI) for information and compliance of orders above.
- The Collector-cum-Addl. Commissioner (ST&E), South Zone, Shimla-09, for information and further necessary action.
- 3. Addl. Commissioner (D)/Excise Branch, HQ for information.
- Dy. Commissioner State Taxes & Excise District Sirmour at Nahan for information and further necessary action.
- Shri Sameer Thakur, Advocate and Shri Tarun Shrivastava, Technical Director, authorized representatives.
 - 6. Shri Sandeep Mandyal, Legal Cell, HQ, Shimla-09.
 - 7. IT Cell for uploading the orders on DoST&E portal.

Reader to the Excise Commissioner Himachal Pradesh