

**BEFORE THE EXCISE COMMISSIONER
HIMACHAL PRADESH**

Case No. 12/2021-22
Date of Institution: 07-12-2021
Date of Order: 09-12-2021

IN THE MATTER OF: -

Excise Commissioner Himachal Pradesh
Vs
M/s Orison Pharma International
Village Khari, Mauza Ogli, Kala Amb,
District Sirmour, Himachal Pradesh
(Licensee MD-VI)

Parties Represented by:-

1. Shri Wishve Bhaskar, ACST&E (Legal Cell) for the Department.
2. S/Sh. Archit Singla, Chartered Accountant and Tarun Srivastava, Technical Director, M/s Orison Pharma for the noticee.

ORDER

**(Under Rule 53 (2) of the Himachal Pradesh Narcotic Drugs and
Psychotropic Substances Rules, 1989)**

1. On contravention of the conditions provided under rule 50 (2) of the Rules above, the licensee above was issued a notice on dated 07-12-2021, under Rule 53 of the Himachal Pradesh Narcotic Drugs and Psychotropic Substances, Rules, 1989. In response to notice above S/Sh. Archit Singla, Chartered Accountant and Tarun Srivastava, Technical Director, M/s Orison Pharma (noticee firm) appeared on behalf of the noticee, who, under the Himachal Pradesh Narcotic Drugs and Psychotropic Substances, Act, 1985, is a holder of License in Form MD-VI.
2. Briefs in the matter are that the premises of the noticee were raided on 30-05-2021 by the officials of Punjab Police along with Drugs Inspectors from Punjab and Nahan in connection with the investigation of the case in F.I.R. No. 196/2021 registered at PS. Ajnala, Amritsar (Rural), District Amritsar, Punjab. A huge quantity of Drug Celcidal 100 SR Tablets (containing Tramadol HCl), manufactured by the noticee was claimed to be marketed by the firm

M/s P.P. Pharma, A-1, Park Plaza, Bandra East, Mumbai. The noticee could not produce the requisite documents/records in respect of drugs in question before the investigating team and it was, also, observed that the noticee could not produce any records and agreements with the marketing firm required under the Drugs and Cosmetics Act and Rules.

3. The Assistant Drugs Controller-cum-Licensing Authority, BBN vide order dated 15-06-2021 cancelled/withdrawn all the product permissions granted to the noticee firm to manufacture the drug formulations containing Codeine Phosphate, Clonazepam, Alprazolam, Diazepam, Zolpidem, Nitrazepam, Chlordiazepoxide, Lorazepam, Etizolam and any other substance which are listed under the NDPS Act. Permission to manufacture formulations containing Tramadol Hydrochloride was already cancelled at the request of the noticee firm.
4. For the irregularities noticed above, a notice was, accordingly, issued to the licensee under Rule 54 of the Narcotic Drugs and Psychotropic Substances, Rules, 1989 as the license in Form MD-VI in respect of noticee had become liable for suspension. However, under proviso to Rule 54 of the Rules above, the noticee was given reasonable opportunity of showing cause against the proposed suspension.
5. The matter was heard at 11:00AM today. S/Sh. Archit Singla, Chartered Accountant and Tarun Srivastava, Technical Director, M/s Orison Pharma (noticee firm), for the noticee submitted that the firm M/s Orison Pharma International, Kala Amb is having valid license holder in Form MD-IV under the HPNDPS Rules 1989. It was also submitted that Celcidal SR 100 mg Tablets (Tramadol Hydrochloride Tablets) B. No.-21A-T128, Mfg. Date-Apr 2021, Exp. Date- June 2021, 4500 tablets were recovered by PS Ajnala. PS Ajnala issued Notice U/s 91 of CrPC with reference to FIR No.196 dated 29/05/2021 under the NDPC Act. Reply was submitted within the stipulated time and as per Letter of SP Amritsar Rural vide no.324-SAP dated 07/11/2021, Mr. Rakesh Goyal's name in FIR has wrongly been written. It was further submitted by the representatives that their factory premises was raided on 30/05/2021 (Sunday).
6. It was further submitted on behalf of the noticee that the firm has after taking various documents like Drugs license, GST and PAN which

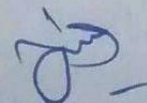
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were issued by the competent Govt. authorities and those said documents authorized M/s Shiva Traders, Delhi for purchase of medicines. The Purchase Order was given on dated 23/04/2021 by M/s Shiva Traders, Delhi. It was also requested by the firm that the marketing address on the product may be mentioned as M/s, P.P. Pharma, A-1, Park Plaza, Bandra (E) Mumbai.

7. It was also contended that the noticee firm has filed an appeal to the Worthy Principal Secretary, Health against the order passed by the Asst. Drugs Controller- cum Licensing Authority, HQ-Baddi, Distt. Solan (HP), vide order no. HWF-H (drugs) 249/02 Vol-II (Loose) 2776 dated 15.6.2021 in respect of drug formulation containing codeine Phosphate, Clonazepam, Alprazolam, Diazepam, Zolpidem, Nitrazepam, Chlordiazepoxide, Lorazepam, Etizolam and other substance as listed under NDPS Act.
8. It was requested for the licensee to not to suspend the license in Form MD-IV until appeal and investigation is under going.
9. Shri Wishve Bhaskar, ACST&E (Legal Cell) for the Department submitted that as the permission to manufacture the drug formulations containing Codeine Phosphate, Clonazepam, Alprazolam, Diazepam, Zolpidem, Nitrazepam, Chlordiazepoxide, Lorazepam, Etizolam and any other substance which are listed under the NDPS Act, has been cancelled/withdrawn by the Assistant Drugs Controller-cum-Licensing Authority, BBN vide order dated 15-06-2021, therefore, for want of recommendations of the State Drug Controller, Himachal Pradesh, and for the breach of conditions as mandated under Rule 50 (2) of the HPNDPS Rules, 1989 license in Form MD-VI of the noticee has to be suspended.
10. The parties were heard and the matter for orders was listed for 12:15PM.
11. I have heard both the parties in the matter. Perusal of the record in the matter reveals that the premises of the noticee were raided by the competent authorities during the investigation of a case registered in Punjab. A firm M/s P.P. Pharma, A-1, Park Plaza, Bandra East, Mumbai was found marketing the products manufactured by the noticee, without requisite documents and authorization (MD-III and/or MD-IV). The noticee, also, could not produce the requisite documents/records in respect of drugs in

question before the investigating team and it was, also, observed that the noticee could not produce any records and agreements with the marketing firm, as well, contrary to required provisions under the Drugs and Cosmetics Act and Rules. It is also revealed from the record that the Assistant Drugs Controller-cum-Licensing Authority, BBN vide order dated 15-06-2021 has cancelled/withdrawn all the product permissions granted to the noticee firm to manufacture the drug formulations containing Codeine Phosphate, Clonazepam, Alprazolam, Diazepam, Zolpidem, Nitrazepam, Chlordiazepoxide, Lorazepam, Etizolam and any other substance which are listed under the NDPS Act. The noticee firm was also not authorized to manufacture Tramadol Hydrochloride as permission to manufacture the above product was already cancelled at the request of the noticee firm, itself. It is clear that as on the date (01-06-2021) of renewal of license in Form MD-VI for the year 2021-22, the noticee was not having the necessary recommendations of the State Drug Controller, Himachal Pradesh, therefore, in view of the provisions of Rule 50 of the HPNDPS Rules, 1989 (read with section 10 of the NDPS Act, 1985) for non-fulfillment of conditions above, the license in Form MD-VI cannot survive and the same stands automatically/deemed suspended w.e.f. 15-06-2021, the date of withdrawal of permission to manufacture drug formulations containing Codeine Phosphate, Clonazepam, Alprazolam, Diazepam, Zolpidem, Nitrazepam, Chlordiazepoxide, Lorazepam, Etizolam and any other substance which are listed under the NDPS Act, including Tramadol Hydrochloride.

12. In view of above the license in Form MD-VI issued to M/s Orison Pharma International, Kala Amb is hereby suspended.
13. Inform all the concerned.
14. File after completion be consigned to records. Record requisitioned from other authorities be returned, respectively.



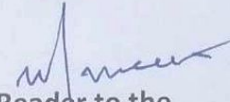
**Excise Commissioner,
Himachal Pradesh**

Endst. No. DoST&E/EC-Reader/2021-22/ 35871-35877
Shimla-171009

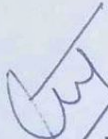
Dated: 09-12-2021

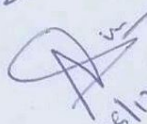
Copy for to:

1. M/s Orison Pharma International, Village Khari, Mauza Ogli, Kala Amb, District Sirmour, Himachal Pradesh (Licensee MD-VI) for information and compliance of orders above.
- ✓ 2. The Collector South Zone, Shimla-09, for information and report compliance of orders.
3. Addl. Commissioner (D)/Excise Branch, HQ.
4. The Dy. Commissioner State Taxes & Excise District Sirmour at Nahan for information and to ensure compliance of orders forthwith.
- 5) Shri Archit Singla CA, Tarun Shrivastava Bhasikal ACSTEE (D) Cell
6. Shri Rakesh Rana, DD (L), Legal Cell, HQ, Shimla-09. Shri Wishve Bhasikal ACSTEE (D) Cell
7. IT Cell for uploading the orders on DoST&E portal.


Reader to the
Excise Commissioner
Himachal Pradesh

Received copy of orders:


09/12/2021


09/12/2021