

**BEFORE THE COMMISSIONER OF STATE TAXES &
EXCISE-CUM-EXCISE COMMISSIONER
HIMACHAL PRADESH**

Case No.: 06/2024

Date of Institution: 21-05-2024

Date of Order: 03-07-2024

IN THE MATTER OF:

M/s Smilax Pharmachem Drugs Industries, Plot No. 33-34,
EPIP-II, Thana, Baddi, District Solan (HP)
(MD-VI, Licensee, Year 2024-25)

Parties Represented by:-

1. Sh. Bhupinder Singh, ACST&E (Legal Cell) for the Department.
2. S/Sh. Vinod Kumar Choudhary, Manager (Accounts), M. B. Goyal, Chairman, Smilax Group and Bal Mohan Sharma, General Manager, Smilax Group, for the Noticee-Licensee.

ORDER

**(Under Rule 50 of the Himachal Pradesh Narcotic Drugs and Psychotropic
Substances Rules, 1989)**

1. This order shall dispose of the proceedings initiated in pursuance of Show Cause Notice issued 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").
2. The brief facts in the case are that M/s Smilax Pharmachem Drugs Industries, Plot No. 33-34, EPIP-II, Thana, Tehsil Baddi, District Solan (HP), (hereinafter referred to as "the noticee") is a License holder in Form MD-VI, granted by this Department under the Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989.
3. In reference with investigation in FIR No. 31 of 2024, dated 20-02-2024, registered under Sections 22, 25, 27-A and 29 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (hereinafter referred to

as "the Act") at Police Station, STF SAS Nagar Mohali (Pb.), the Assistant Drugs Controller-cum-Licensing Authority, O/o the State Drug Controller, Himachal Pradesh, Baddi, District Solan (HP) vide order No. HFW-H(Drugs) 04/16-3527, dated 14-05-2024, cancelled, with immediate effect, noticee firm's License No. MNB/18/1044 and MB/18/1045 vis-à-vis product licenses/permission of all the drugs containing any active pharmaceutical ingredient which has a dual presence in Narcotics Drugs & Psychotropic Substances Act as well as in the Drugs & Cosmetics Act, 1940 and Rules 1945 made there under, in respect of the noticee firm.

4. Now, for the violations of the terms and conditions of the granted license MD-VI and in accordance with the provisions as contained under proviso to Rule 50 of the Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989, the license of the noticee firm above has become liable for revocation or suspension under proviso to Rule 54(1) of the HPNDPS Rules, 1989.
5. The Noticee, as per mandate of the proviso to Rule 54 (1) of the HP NDPS Rules, 1989, was accordingly provided an opportunity of being heard in the matter.
6. Shri Vinod Kumar Choudhary, Manager (Accounts), Shri M. B. Goyal, Chairman, Smilax Group and Shri Bal Mohan Sharma, General Manager, Noticee firm appeared in the matter and admitted that investigation in FIR No. 31 of 2024, mentioned above, pertains to Tramadol HCL, a psychotropic substance under the provisions of the NDPS Act, 1985 read with Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989. It was also submitted for the noticee that FIR is not related to codeine phosphate for which MD-VI has been issued. The Noticee admitted that the Assistant Drugs Controller-cum-Licensing Authority, O/o the State Drug Controller, Himachal Pradesh, Baddi, District Solan (HP) vide order No. HFW-H(Drugs) 04/16 3527 dated 14-05-2024 has cancelled, with immediate effect, the noticee firm's License No. MNB/18/1044 and MB/18/1045 vis-à-vis product licenses/permission of all the drugs containing any



active pharmaceutical ingredient which has a dual presence in Narcotics Drugs & Psychotropic Substances Act, as well as, in the Drugs & Cosmetics Act, 1940 and Drug Rules 1945, made there under, in respect of the noticee firm i.e. M/s Smilax Pharmachem Drug Industries, Plot No. 33-34, EPIP-II, Thana, Baddi, District Solan (HP). The Noticee informed that now the Assistant Drugs Controller-cum-Licensing Authority O/o States Drugs Controller Baddi, Distt. Solan vide his office letter no. HFW-H (Drugs) 04/16-3901 dated 10/06/2024 has revoked the "Stop Manufacturing" Order, which was issued vide letter no. HFW-H (Drugs) 04/06-3910-19 dated 27.05.2024. The Noticee, further admitted that, as on today, it is not in possession of the necessary recommendation under Rule 50 (1) of the HPNDPS Rules, 1989, from the State Drug Controller as is mandatory for the grant of a Chemist's license in Form MD-VI. Though the noticee submitted that all the cancelled licenses under the Narcotics Drugs & Psychotropic Substances Act, 1985 as well as in the Drugs & Cosmetics Act, 1940 and Drug Rules 1945 are being revoked by the concerned Department, and sought time to produce the same. It was requested for the licensee that the license MD-VI may not, therefore, be revoked or suspended.

7. Noticee-Licensee was granted a weeks' time to show the necessary documents and permission.
8. Sh. Bhupinder Singh, ACST&E (Legal Cell) for the Department, submitted that the cancelled product licenses/permission of all the drugs containing any active pharmaceutical ingredient which has a dual presence in Narcotics Drugs & Psychotropic Substances Act has yet not been revoked, therefore, the Noticee MD-VI License may be revoked.
9. I have heard both parties in the matter and gone through the case record. The noticee has admitted having violated the provisions of the NDPS Act, 1985 read with HPNDPS Rules, 1989 and, thus, the terms and conditions of MD-VI license are also violated. The documents available on record also reveal that the Assistant Drugs Controller-cum-Licensing Authority, BBN vide order dated 14-05-2024 has

cancelled/withdrawn all the product permissions granted to the noticee firm to manufacture the drug formulations containing narcotic substance. The gravity of the offences committed and admitted by the notice-licensee apart, it is evident that licenses/permission granted, under the Drugs and Cosmetics Act, 1940 and Drug Rules, 1945, to the noticee/licensee firm to produce drugs containing any active pharmaceutical ingredient, which has a dual presence in Narcotics Drugs & Psychotropic Substances Act, has yet not been revoked by the competent authority. Therefore, for the below given provisions under Rule 50 (1) and 54 of the HPNDPS Rules, the license granted in Form MD-VI to the noticee-License is also automatically deemed revoked (cancelled) w.e.f. 14-05-2024 (the date of cancellation of licenses under the Drugs and Cosmetics Act, 1940 and Drug Rules, 1945):

“50(1) The Excise Commissioner or any other officer specifically empowered by him in this behalf, may on the recommendation of the State Drug Controller, Himachal Pradesh; grant a Chemist's license in Form MD-VI, to any person, on payment of a fee of rupees one lakh fifty thousand 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):”

“54. Revocation or suspension of licence or permit.-(1) Any license or permit granted under these rules may be revoked or suspended by the licensing authority if the holder or any person employed by him is found to have committed a breach of the conditions thereof or any of the provisions of these rules, or has been convicted of an offence under the Act or any offence under the Indian Penal Code:”

It is clear that as on this date (03-07-2024), the noticee, despite having given time to show the same, is not having the necessary license/recommendations under the Drugs and Cosmetics Act, 1940 and Drug Rules, 1945, issued by the State Drug Controller of Himachal Pradesh. The noticee has also failed to show documents regarding

revocation of licenses cancelled by the Assistant Drugs Controller-cum-Licensing Authority, O/o the State Drug Controller, Himachal Pradesh, Baddi, District Solan (HP) vide order No. HFW-H(Drugs) 04/16 3527 dated 14-05-2024. 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-fulfilment of conditions above, the license in Form MD-VI cannot survive and the same stands automatically/deemed revoked (cancelled) w.e.f. 14-05-2024, the date of withdrawal of permission to manufacture drug formulations containing any active pharmaceutical ingredient which has a dual presence in Narcotics Drugs & Psychotropic Substances Act as well as in the Drugs & Cosmetics Act, 1940 and Rules 1945. Hence, the license in Form MD-VI is cancelled accordingly.

10. In view of order passed above, the competent authority i.e. Deputy Excise and Taxation Commissioner {Now Addl. Commissioner State Taxes & Excise (South Zone)} is directed to take further necessary action in the matter as per relevant provisions of the Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989 with special reference to Rule 50 (2) (xiv) of the Rules ibid.
11. Inform all the concerned and file after completion be consigned to records. Record requisitioned from other authorities be returned.


**Excise Commissioner,
Himachal Pradesh**

Endst. No. EXN/CoST&E- EC (NDPS)-Reader/2024/17147-52 Shimla 171009

Dated: 03-07-2024

Copy for information to:

1. M/s Smilax Pharmachem Drugs Industries, Plot No. 33-34, IPIP-II, Thana, Baddi, District Solan (HP) (MD-VI, Licensee, Year 2024-25) for information and compliance of orders above.
2. The State Drugs Controller, Controlling-cum-Licensing Authority, Himachal Pradesh, Baddi, District Solan (HP).
3. The Collector-cum-Addl. Commissioner (ST&E), South Zone, Shimla-05, for information and further necessary action.