

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

Case No.: 16/2024

Date of Institution: 13-06-2024

Date of Order: 04-07-2024

IN THE MATTER OF:

M/s Smilax Healthcare Drug Co., Plot No. 23, EPIP-I, Jharmajri,
Baddi, District Solan (HP)
(MD-VI, Licensee, Year 2024-25)

Parties Represented by:-

1. Sh. Bhupinder Singh, ACST&E (Legal Cell), (HQ) for the Department.
2. Sh. Bal Mohan Sharma, General Manager, Smilax Group, for the 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 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 Healthcare Drug Co., Plot No. 23, EPIP-I, Jharmajri, Tehsil Baddi, District Solan (HP), (hereinafter referred to as "the licensee") 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 order in investigation report in respect of above Licensee M/s Smilax Healthcare Drugs Co., Plot No. 23, EPIP-I, Village Jharmajri, Tehsil Baddi, District Solan (HP), the Assistant Drugs

Controller-cum-Licensing Authority, O/o State Drugs Controller, Baddi, District Solan (H.P.) communicated to this Department that vide order No. HFW-H(Drugs) 04/16-3855, dated 22-05-2024, the License No. MNB/15/901 and MB/15/902 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 above firm M/s Smilax Healthcare Drugs Co. Plot No. 23, EPIP-I, Jharmajri, Baddi, Solan (HP) has been cancelled.

4. Due to the cancellation of licenses above under the NDPS Act, Drugs & Cosmetics Act, 1940 and Drug Rules, 1945, there is a violation, by the Licensee above, of the terms and conditions of the license granted in Form MD-VI under the Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989 and for non compliance with the provisions as contained under proviso to Rule 50 of the Rules above, the license in Form MD-VI of the above firm has also become liable for revocation or suspension under Rule 54(1) of the HPNDPS Rules, 1989.
5. In order to afford opportunity of being heard as provided under proviso to Rule 54 (1) of the HPNDPS Rules, 1989, the submissions of the licensee, as are there on record, in similar matters, are 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 replying licensee that FIR is not related to codeine phosphate for which MD-VI has been issued. The licensee 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 3855 dated 22-05-2024 has cancelled, with immediate effect, the licensee firm's License No. MNB/15/901 and MB/15/902 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 Licensee i.e. M/s Smilax Healthcare Drug Co., Plot No. 23, EPIP-I,

Jharmajri, Baddi, District Solan (HP). The licensee, 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 licensee 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.

6. The Licensee as well as Department was granted two weeks' time to show the necessary documents, permissions and submissions.
7. 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, licensee's MD-VI License may be revoked.
8. The submissions of both the parties are taken into consideration. I have also perused the case record. The licensee 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 22-05-2024 while cancelling License No. MNB/15/901, MB/15/902, has cancelled/withdrawn all the product permissions granted to the licensee firm to manufacture the drug formulations containing narcotic substance. Vide order *ibid*, the authority has also cancelled all other loan licenses in respect of the above parent licensee firm. 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 licensee firm to produce drugs containing any active pharmaceutical ingredient, which has a dual presence in Narcotics Drugs & Psychotropic Substances Act, has 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, under the HPNDPS Rules, 1989, to the Licensee becomes liable to be deemed revoked (cancelled) w.e.f. 22-05-2024 (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 (04-07-2024), the licensee, 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 licensee has also failed to show documents regarding revocation of license No. MNB/15/901, MB/15/902, 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 3588 dated 22-05-2024. 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 deemed revoked (cancelled) w.e.f. 22-05-2024, 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, hereby, 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.

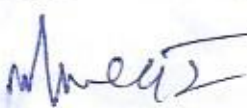

**Excise Commissioner,
Himachal Pradesh**

Endst. No. EXN/CoST&E- EC (NDPS)-Reader/2024/17242-247 Shimla 171009

Dated: 04-07-2024

Copy for information to:

1. M/s Smilax Healthcare Drug Co., Plot No. 23, EPIP-I, Jharmajri, 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. Addl. Commissioner ST&E(D), HQ for necessary action.
4. The Collector-cum-Addl. Commissioner (ST&E), South Zone, Shimla-05, for information and further necessary action.
5. Dy. Commissioner State Taxes & Excise RD BBN for information and further necessary action.
6. Legal Cell, HQ, Shimla-09.


Reader