

**CWP-28692-2018**

1

**IN THE HIGH COURT OF PUNJAB AND HARYANA
AT CHANDIGARH****207****CWP-28692-2018****Date of Decision : March 06, 2025****ROYAL INTERNATIONAL****-PETITIONER****V/S****STATE OF PUNJAB AND ANOTHER****-RESPONDENTS****CORAM: HON'BLE MR. JUSTICE KULDEEP TIWARI**

Present: Mr. Akshay Jain, Advocate and
Ms. Shilpa Thakur, Advocate
for the petitioner.

Mr. Sahil R. Bakshi, A.A.G., Punjab.

Ms. Geetika Sharma, Advocate for
Mr. Sourabh Goel, Advocate
for the respondent No.3- NCB.

*********KULDEEP TIWARI, J. (ORAL)**

1. The challenge enclosed in the instant writ petition, is to the order dated 08.11.2017 (Annexure P-8), whereby, the respondent No.2- Licensing Authority-cum-Joint Commissioner (Drugs), Food and Drugs Administration, Punjab (hereinafter referred to as the 'licensing authority'), in exercise of the powers conferred by Rule 66 of the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the 'Rules of 1945'), suspended the petitioner's purchase and sale of the drug formulations involving Tramadol Hydrochloride tablets.

REASONS FOR PASSING THE IMPUGNED ORDER

2. Before this Court proceeds to gauge the validity of the



impugned order, it is deemed appropriate to first capture the reasons whereon the impugned order has been banked upon.

3. What emerges from a studied survey of the impugned order is that, the licensing authority received an official communication from the Narcotics Control Bureau regarding dome diversions of the Tramadol formulations sold/exported by the petitioner. Consequently, in view of public interest, in order to prevent the misuse of the formulation in question and in order to ensure impartial investigation, the licensing authority passed the impugned suspension order under the provisions of Rule 66 of the Rules of 1945.

FACTUAL MATRIX

4. The petitioner, which is a proprietorship firm dealing in import and export of drug formulations, was granted licence(s) by the licensing authority in Forms 20 and 21 of Schedule A of the Rules of 1945. The petitioner was granted wholesale licence(s) for drugs specified in various Schedules, except Schedule X of the Rules of 1945. Since the petitioner was having wholesale licence(s), therefore, it got the formulations manufactured from one M/s Ramson Remedies, after getting the purchase orders in its name at the first instance, and subsequently, issuing the purchase orders to the manufacturer (supra). Moreover, since the drug formulations were to be exported from the country, hence permission/No Objection Certificate was required to be obtained from the Central Drugs Standard Control Organization, North Zone, Government of India, Ghaziabad (hereinafter referred to as the 'CDSCO'). Accordingly, the requisite permission/No



Objection Certificate in relation to the formulation containing Tramadol Hydrochloride BP of various strengths was obtained by the manufacturer from the CDSCO. Similar permission/No Objection Certificate was obtained by the manufacturer from CDSCO in respect of specific purchase orders from M/s Perfect Trading LLC, Dubai.

5. The manufacturer, i.e. M/s Ramson Remedies, vide its invoice dated 07.11.2017, supplied/sold formulation of Tramadol Hydrochloride of a particular strength to the petitioner and immediately after receipt of the consignment, the petitioner was served with the impugned order/notice by the licensing authority, whereby, its purchase and sale of the drug formulations involving Tramadol Hydrochloride tablets was suspended.

SUBMISSIONS OF THE LEARNED COUNSEL FOR THE PETITIONER

6. The learned counsel for the petitioner, in his endeavour to assail the impugned order, submits that, the same has been drawn in gross violation of Rule 66 of the Rules of 1945 inasmuch as the said Rule makes it upon the licensing authority to, before drawing the impugned order, issue show cause notice to the petitioner, however, nothing of this sort happened. Consequently, the impugned order is not sustainable in the eyes of law.

7. The learned counsel for the petitioner next submits that, in the enquiry conducted by the Zonal Licensing Authority, Amritsar and Gurdaspur, a positive finding has been recorded to the effect that, the petitioner and also the manufacturer of the drug formulation had manufactured it for sale for export purposes only, and that too, only after

**CWP-28692-2018**

4

obtaining approval from the concerned authority of CDSCO and from the State Licensing Authority, Punjab. Hence, this enquiry report makes it apparent that, the petitioner had no role to play in illegal diversion of consignment, if any actually done or reported.

8. Finally, it is submitted by the learned counsel for the petitioner that, the petitioner is suffering huge financial losses on account of the impugned suspension order, inasmuch as, it is unable to execute the already received orders.

SUBMISSIONS OF THE LEARNED STATE COUNSEL

9. The submissions made by the learned counsel for the petitioner are vociferously opposed by the learned State counsel and he raises objection even with regard to maintainability of the instant writ petition, on the ground that, the petitioner is seized of an efficacious statutory remedy.

10. Furthermore, the learned State counsel submits that, the Government of India, Ministry of Home Affairs, Narcotics Control Bureau, West Block-I, Wing No. V, R.K. Puram, New Delhi, vide its secret communication bearing F. No. VII/2/12/8/2017 Int. dated September, 2017, brought it to the notice of the licensing authority that, the petitioner provided total 70,00,000 tablets of Tramadol along with other items to Perfect Trading LLC, Dubai, which are suspected to have been illegally diverted by the latter/trading company for use by Islamic State in Iraq and Syria (ISIS), a terrorist organization operating in Libia.

11. The learned State counsel next submits that, a joint enquiry was conducted by the respondent(s) whereupon it was found that, malpractices

**CWP-28692-2018**

5

were involved in the manufacturing of drug formulation tablet Tramadol HCL, and as a consequence thereof, the permission for manufacturing of drug formulation (supra) by the petitioner has been cancelled vide order dated 18.01.2018, which is enclosed as Annexure R-III with the reply dated 20.12.2019.

12. Concluding his arguments, the learned State counsel submits that, after amendment, the drug Tramadol has been included in the list of psychotropic substances under the N.D.P.S. Act, vide notification dated 26.04.2018. Therefore, for its sale and distribution for export purpose, the petitioner must obtain approval from the NCB before applying for permission from the licensing authority, which has, in fact, not been done by the petitioner in the present case.

REASONS FOR DISMISSING THE INSTANT WRIT PETITION

13. This Court has considered the submissions made by the learned counsels for the contesting litigants and also made studied survey of the record. What emerges from the record is that, in the joint enquiry conducted by the respondent(s), malpractices were found on the part of the petitioner, in the manufacturing of drug formulation tablet Tramadol HCL. Consequently, the permission for manufacturing of drug formulation (supra) by M/s Ramson Remedies has been cancelled vide order dated 18.01.2018.

14. Furthermore, as of today, the drug Tramadol has been included in the list of psychotropic substances under the N.D.P.S. Act, vide notification dated 26.04.2018. Hence, for the purpose of sale/distribution of drug (supra) for export purpose, the distributor(s)/petitioner is required to

**CWP-28692-2018**

6

obtain approval from the NCB before applying for permission to the licensing authority.

15. Moreover, this Court has also considered the grave concern raised by the Ministry of Home Affairs regarding diversion of Tramadol tablets, as got manufactured by the petitioner, to the Islamic State in Iraq and Syria (ISIS), a terrorist organization operating in Libia.

16. In summa, the instant writ petition is **dismissed**. However, liberty is reserved to the petitioner to challenge the licence cancellation order dated 18.01.2018 before the appropriate authority/forum.

March 06, 2025
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(KULDEEP TIWARI)
JUDGE

Whether speaking/reasoned	:	Yes/No
Whether Reportable	:	Yes/No