

(2016) 07 CAL CK 0032

In the Calcutta High Court

Case No : Writ Petition No.10109 (W) of 2016 with Writ Petition No.10110 (W) of 2016

Pankaj Shukla

APPELLANT

Vs

Union of India and Others

RESPONDENT

Date of Decision : 14-07-2016

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 3(b)

Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS) — Section 67, 80

Citation : (2016) 4 CalHCN 233

Hon'ble Judges : Joymalya Bagchi, J.

Bench : Single Bench

Advocate : Sudipta Maitra, Kishore Datta, Souvik Mitra, Ms. Sumita Shaw, Advocates, for the Appellant; Pinaki Bhattacharyya, Advocate, Ms. Srilekha Bhattacharyya, Advocate, for the Respondent

Final Decision : Disposed Off

Judgement

Joymalya Bagchi, J.—Petitioner is a clearing and forwarding agent of M/s. Abbott Healthcare Pvt. Ltd. and has valid licence to deal with various drugs including phensedyl cough syrup.

2. By a notification dated 10th March, 2016 the Central Government banned combinations of 344 fixed dose combination including combination of phensedyl cough syrup. Such notification according to the petitioner is the subject matter of challenge in Delhi and other High Courts. I am further informed that before the Delhi High Court the Union of India informed the said Court that instructions had been issued to the State authorities not to implement the said notification. Such information was also uploaded on the website of Drug Controller General of India.

3. Under such circumstances, the petitioner has sought a declaration that phensedyl cough syrup cannot be treated as a "narcotic drugs" or "psychotropic substance" or a "manufactured drugs" under the Narcotic Drugs and Psychotropic Substances Act, 1985. Reliance is placed in that regard to Item

No.35 of 159 the notification being SO826(E) dated 14.11.1985 issued by the Central Government as follows:

"S.O. 826 (E), dated 14th November, 1985 - In exercise of the powers conferred by sub-clause (b) of clause (xi) of Section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby declares the following narcotics substance and preparation to be manufactured drugs, namely:

.....

(35) Methyl morphine (commonly known as 'Codeine') and Ethyl morphine and their salts (including Dionine), all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration not more than 2.5 per cent in undivided preparations and which have been established in therapeutic practice."

4. Reliance has also been placed on the order dated 26th October, 2005, issued by the Drugs Controller General of India which reads as follows:

"As you are aware there are number of Cough preparations like Corex of M/s. Pfizer Limited, Mumbai, Phensedyl of M/s. Nicholas Piramal India Limited, Mumbai, Codokuff of M/s. German Remedies, Codeine Linctus of M/s. Zydus Alidac etc. moving in inter state commerce. These preparations contain among other drugs Codeine Phosphate 10mg as one of the ingredients. By virtue of the fact that these preparations contain Codeine and its salts they do not fall under the provisions of NDPS Act and Rules of 1985 but they fall under Schedule H of the Drugs & Cosmetics Rule and are governed by the said rules. Though stocking and sale of these drugs do not attract the provisions of NDPS Act and Rules 1985 however these formulations are prescription drugs and are to be dispensed on the prescription of a registered Medical Practitioners only. Further you may be already aware that under notification number S.O. 826 (E) dated 14th Nov. 1985 under the Narcotic Drugs and Psychotropic Substances Act and Rules 1985 certain preparations are exempted as manufactured drugs provided the preparations contain the Narcotic drug to the extent permitted. In respect of Codeine under entry no. 35 it is stated that Codeine and Ethyl Morphine and their salts including Dionine all dilutions and preparations are considered to be manufactured drugs except those which are compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 per cent in undivided preparations and which have been established in therapeutic practice."

The above brought to your notice for information and necessary action."

5. Similar clarification dated March, 2009, was issued by Drug Controller General of India which reads as follows:-

Subject:- Request for clarification of drug substance Cough Linctus containing

Codeine Phosphate - Regarding

Sir,

Please refer to your letter no nil dated the 13th March, 2009 seeking clarification as to whether cough preparations containing codeine phosphate 10 mg or less falls under NDPS Act and the Rules or Drugs and Cosmetics Act and the Rules thereunder.

In this connection this Directorate had already issued a circular letter vide our letter number X-11029/27/05-D dated 26/10/2005 to all State Drugs Controllers with a copy to various associations and a copy Narcotic Control Bureau New Delhi (copy enclosed). The above circular inter alia stated that these preparations (Cough Linctus containing Codeine Phosphate) contains among other drugs Codeine Phosphate 10mg as one of the ingredients. By virtue of the fact that these preparations contain Codeine and its salts they do not fall under the provisions of NDPS Act and the Rules of 1985 but they fall under Schedule H of the Drugs and Cosmetic Rules and are governed by the said rules. Though stocking and sale of these drugs do not attract the provisions of NDPS Act and Rules 1985, however these formulations are prescriptions drugs and are to be dispensed on the prescription of a registered Medical Practitioner only.

Further you may be aware that under notification number S.O.826 (E) dated 14th November, 1985 under the Narcotic Drugs and Psychotropic Substances Act and Rules 1985 certain preparations are exempted as manufactured drugs provided the preparations contain the Narcotic drug to the extent permitted. In respect of Codeine under entry no.35 it is stated that Codeine and Ethyl Morphine and their salts including Dionine all dilutions and preparations are considered to be manufactured drugs except those which are compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosages unit and with a concentration of not more than 2.5 per cent in undivided preparations and which have been established in therapeutic practice.

6. It appears from the aforesaid notifications and/or clarifications that codeine and its preparations including salts are manufactured drugs under NDPS Act save and except under the following conditions:-

(i) When codeine is compounded with one or more other ingredients and does not contain more than 100 milligrams of the drug per dosages unit and with a concentration of not more than 2.5% in undivided preparations, and

(ii) is not used in therapeutic practice.

7. In *Md. Sahabuddin & Anr. v. State of Assam* reported in (2012) 119 AIC 45 (SC) the Apex Court, inter alia, held that if codeine phosphate was transported illegally without licit documents it cannot be presumed that it was for therapeutic practice in spite of being a Schedule H drug. Section 80 of the NDPS Act, inter alia, provides that the provisions of the said Act shall be in addition to the Drugs

and Cosmetics Act, 1940 or rules framed thereunder. Hence, the provisions of both the legislations are to be read harmoniously and in the event codeine or its preparations including salts which fall within the ambit of Schedule H drug is possessed stored, transported or purchased under suspicious circumstances which give rise to a reasonable suspicion that the drug is not being used for therapeutic purposes, the provisions of the NDPS Act can be invoked. That apart, any question as to the concentration of the seized phensedyl cough syrup is a matter of investigation and the same cannot be decided in exercise of this jurisdiction.

8. In the present case, I have been informed that the petitioner has duly offered himself to interrogation pursuant to the notices under Section 67 of the NDPS Act.

9. Learned counsel appearing for Union of India submits that no incriminating material has been collected against the petitioner till date.

10. In view of the aforesaid circumstances, both the writ petitions are disposed of observing that the petitioner shall cooperate with the investigation in accordance with law and he would have liberty to agitate all his grievances in accordance with law at an appropriate stage of the proceeding, if occasion so arises.

11. With the aforesaid observation, both the writ petitions are disposed of.