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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% **Reserved on: 06th September, 2022**
Pronounced on: 16th September, 2022

\+ **BAIL APPLN. 1136/2021**

MOHD AHSAN ..... Petitioner
Through: Mr. Amjad Khan and Mr. Aditya Kumar, Advocates.

versus

CUSTOMS ..... Respondent
Through: Mr. Parmod Bahuguna, Advocate

CORAM:
HON'BLE MR. JUSTICE SIDDHARTH MRIDUL
HON'BLE MR. JUSTICE AMIT SHARMA

JUDGMENT

AMIT SHARMA J.

1. The following questions have been referred to this Bench by a learned Single Judge of this Court:

> *"a) whether in cases specifically related to manufactured drug with a **miniscule percentage** of a narcotic substance, the weight of the neutral substance ought to be ignored while determining the nature of the quantity seized i.e. small, commercial or in between?*
> *b) whether Note 4 of the S.O. 1055 (E) dated 19th October, 2001 published in the Gazette of India,*

> *Extra., Pt.II, Sec3 (ii) dated 19th October 2001, as amended on 18.11.2009, should be held inapplicable to manufactured drug which contain a* ***miniscule percentage*** *of a narcotic drug?*
> *c) whether Note 4 of the S.O. 1055 (E) dated 19th October, 2001 published in the Gazette of India,. Extra., Pt.II, Sec3 (ii) dated 19th October 2001, as amended on 18.11.2009, should be made applicable to cough syrups containing* ***miniscule percentage*** *of Codeine since it has medicinal value and is also easily available?"*

2. The background for such reference is that during the course of the hearing in the bail application, filed on behalf of the petitioner, in a Complaint Case No. 62/2020, dated 31.01.2018, filed by customs under Sections 21(C) and 23(C) of The Narcotic Drugs and Psychotropic Substances Act 1985 (hereinafter "NDPS Act"), one of the points that arose for consideration was whether the recovery of 110 bottles of 'Phensedyl New' weighing 100 gms each and having a Codeine concentration of 0.17% per bottle would be considered as 'commercial quantity' under the NDPS Act.

3. The attention of the learned Single Judge was drawn to a judgment of another learned Single Judge of this Court in Iqbal Singh vs. State (BAIL APPLN. 645/2020), wherein the learned Single Judge vide order dated 31.07.2020 had held that cough syrup bottle (Onerex) containing Codeine Phosphate would fall outside the scope of the definition of 'manufactured drug' under Section 2(xi) of the NDPS Act. The aforesaid finding of the learned Single Judge was based on various provisions of the NDPS Act as well as the Drugs and Cosmetics Act, 1940. The facts of the bail application in Iqbal Singh

(supra) were similar to the facts in the present bail application.

4. The learned counsel for the petitioner in the present bail application relying on the judgment of this court in Iqbal Singh *(supra)* had argued that in the present case too, the bottles which had been recovered were prescribed drugs which are covered under the Drugs & Cosmetics Act and fall under Schedule H of The Drug and Cosmetics Rules, 1945. It was further argued that the said bottles were manufactured by a licensed manufacturer, i.e. M/s Abbot Healthcare Pvt. Ltd.

5. The learned Single Judge, while hearing the present bail application noted that the case of the applicant was to the extent that since each bottle contained only 0.17% Codeine concentration, the same cannot be categorised as 'commercial quantity'. In other words, it was urged on behalf of the petitioner that only the weight of Codeine concentration in each of the bottles should be taken into account, which in the present case would be 18.70 gms (0.17% x 110), bringing the case in the category of 'intermediate quantity' and therefore, rigours of Section 37 of the NDPS Act would not be applicable. The Hon'ble Supreme Court in Hira Singh vs. Union of India, (2020) 20 SCC 272 had considered the notification bearing no. S.O. 2941(E) dated 18.11.2009, adding 'Note 4' to the notification bearing no. S.O. 1055(E) dated 19.10.2001 and had held that irrespective of the quantity of the narcotic drug or psychotropic substance in the mixture, the quantity of the entire substance would be considered for the purposes of ascertaining whether it is a commercial quantity, intermediate quantity or small quantity.

6. After taking into consideration the judgment of Hon'ble Supreme Court in Hira Singh's Case (*supra*), the learned Single Judge in Iqbal Singh (*supra*) held as under:

> *"25. Plainly, the quantity of the mixture of a manufactured drug and a neutral substance would require to be considered for the purposes of determining whether the quantity is a commercial quantity or a small quantity for the purposes of the NDPS Act. However, a drug which is manufactured but falls outside the scope of the definition of a 'manufactured drug' under the NDPS Act on account of the component of offending material being below the prescribed threshold, cannot be construed as a manufactured drug by dissecting its ingredients and considering them in isolation."*

7. In this backdrop, the learned Single Judge, in the present matter vide order dated 25.06.2021 observed as under:

> *"16. A reading of the judgment in Iqbal Singh (supra) therefore shows that this Court has created a distinction between illicit substances which are sold in mixtures containing neutral substances or which may have the effect of enhancing the effect of the offending substance or facilitate its abuse and a non offending substance or preparation with bifacial qualities which may have the miniscule quantities of a substance which are also used for medicinal purposes and are available in medical shops across country."*

The learned Single Judge further observed:

> *"21. Be that as it may, para 8.4 and para 10(II) of the judgment of the Supreme Court in Hira Singh v. Union of India reported as (2020) SCC Online SC 382 does not make any distinction between manufactured*

> *drugs with a miniscule percentage of narcotic substance and other mixture of narcotic drugs or psychotropic substance out of a neutral substance. The judgment of Iqbal Singh (supra) is therefore contrary to a plain reading of the judgment of the Supreme Court. Since cases of this nature are common there is a strong possibility that different Single Judge Benches of this Court may take different opinions while deciding as to whether the rigour of Section 37 would be attracted or not in such cases. It would therefore be in the interest of justice that an authoritative and final pronouncement is made by a larger Bench of this Court."*

It is in these circumstances that the questions referred to hereinabove have been placed before us for decision.

8. Written submissions have been filed on behalf of the petitioner and as well as the respondent.

9. It is submitted on behalf of the petitioner that the 110 bottles of cough syrup 'Phensedyl New' manufactured by M/s Abbot Healthcare Pvt. Ltd., containing a miniscule quantity of Codeine i.e. 0.17% in each of the bottles will not fall within the definition of the 'manufactured drug' under Section 2(xi) of the NDPS Act.

10. The learned counsel for the petitioner relies upon notification titled "Manufactured Narcotics Drug" (as contained in Government of India Notification No. S.O. 826 (E) dated 14.11.1985 and S.O. 40(E) dated 21.09.1993 and S.O. no. 1431 (E) dated 21.06.2011) issued in exercise of powers conferred by Sub-Clause (b) of Clause (xi) of Section 2 of the NDPS Act and draws attention of this Court to Entry 35, which pertains to the substance Methyl Morphine (commonly

known as 'Codeine'). The said entry reads as under:

> *"**S.O. 826(E). – 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 narcotic substances and preparations to be manufactured drugs, namely:-***
> *xxx*
> *35. Methyl morphine (commonly known as 'Codeine') and Ethyle 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 of not more than 2.5% in undivided preparations and which have been established in Therapeutic practice.*
> *xxx"*

11. It was submitted on behalf of the petitioner that the present case is covered under the exception provided for in the aforesaid Entry 35. It was further submitted that the alleged recovery of 110 bottles of cough syrup, measuring 100 ml each contained 0.17% of Codeine Phosphate and therefore it was contended that since Codeine was not more than 100 milligrams in each bottle, the same would not be a 'manufactured drug' under the NDPS Act. In other words, the cough syrup containing Codeine is used for "therapeutic practice" and therefore is not a narcotic drug under the NDPS Act.

12. In view of the foregoing, submissions on behalf of the petitioner was that, the reliance placed upon the judgment of the Hon'ble Supreme Court in Md. Sahabuddin & Anr. vs. State of Assam (2012) 13 SCC 491 by the respondent was not applicable to the facts

and circumstances of the present case as the alleged recovery in Md. Sahabuddin (*supra*) was extremely huge and the Codeine percentage in the cough syrup recovered therein was also 5%, which exceeded the permissible limit of 2.5%.

13. The learned counsel for the petitioner also relied upon an order dated 26.10.2005 issued by the Drug Controller General of India, inter alia, directing as under:-

> *"As you are aware there are number of Cough preparations like Corex of M/s Pfizer Ltd. 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 10 mg as one of the ingredients. By virtue of the fact that these preparations contain Codeine and it salts they do not fall under the provisions of NDPS Act and Rules of 1985 but they fall under Schedule H of the Drugs and Cosmetics Rules and are governed by the said rules."*

14. The learned counsel for the petitioner had primarily relied upon judgment/order passed by learned Single Judge in Iqbal Singh (*supra*). Reliance was further placed on a judgment passed by learned Single Judge of this Court in W.P. (C) 212/2016, titled Pfizer Ltd. & Anr. vs. Union of India & Anr. dated 01.12.2016, whereby a notification issued by the Central Government dated 10.03.2016 which considered cough syrup containing Codeine, as *"likely to involve risk to human beings"* was quashed. Reliance was also placed on an order passed by the Hon'ble Supreme Court in Binod Kumar @ Binod Kumar Bhagat vs. The State of Bihar, (2018) 14 SCC 199 dated 10.08.2017, wherein

it was held as under:-

> *"6. According to the prosecution the Corex cough syrup has been recovered from the godown and the prosecution alleges that it has been recovered from the appellant. It is evident that the Delhi High Court by order dated 01.12.2016 quashed the notification issued under Section 26A of the Drugs and Cosmetics Act, 1940 which has sought to prohibit the manufacture, distribution and sale of 344 Fixed Dose of Combination. The FIR was registered on 23.8.2016. Be that as it may, the appellant has been in custody from 24.08.2016."*
>
> *7. Having regard to the facts and circumstances of the case, we are of the view that it is just and proper to release the appellant on bail. Therefore, we order the appellant to be released on bail on execution of his personal bond in sum of Rs. 25,000/-with two sureties in the like sum to the satisfaction of the trial judge. We permit the trial judge to impose such conditions as he feels necessary for ensuring the appellant's attendance on the dates of posting in the trial court."*

15. It was also submitted by learned counsel for the petitioner that the Hon'ble Supreme Court in the case of Hira Singh *(supra)* was considering a case of a declared narcotic drug and the issue of a miniscule quantity of an alleged narcotic drug like Codeine, used within permissible limits in medicinal products which are available to be bought online and offline with prescriptions, was not under consideration before the Hon'ble Supreme Court.

16. Learned Counsel for the petitioner, on the basis of the aforesaid submissions, prayed for grant of bail to the petitioner in the present matter.

17. Learned SPP appearing on behalf of the respondent submits that the interpretation with regard to the questions referred by the

learned Single Judge is completely covered by the judgment of the Hon'ble Supreme Court in Hira Singh & Anr. vs. Union of India (*supra).*

18. Learned SPP for the customs further relies upon the judgment of the Hon'ble Supreme Court in Md. Sahabuddin (*supra*) wherein the Hon'ble Supreme Court has held that if Codeine Phosphate was being transported illegally without proper documents, it cannot be presumed that it was for therapeutic practice in spite of it being a Schedule H drug. It was further submitted that Section 80 of NDPS Act, inter alia, provides that the provisions in said Act shall be in addition to the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder. It is the contention of the learned SPP that provisions of both legislations are to be read harmoniously and in the event Codeine or its preparations including salts which fall within the ambit of Schedule H is possessed, stored, transported or purchased under suspicious circumstances, the same would give rise to a reasonable suspicion that the drug is not being used for therapeutic purposes, and provisions of the NDPS Act can be invoked.

19. Reliance is also placed by learned SPP on the order/judgment dated 01.11.2017 rendered in Gavranjeet Singh @ Gavrana vs. State by the Hon'ble High Court of Rajasthan in Criminal Misc. Bail No. 3790/2017 wherein the Hon'ble High Court followed the decision of the Hon'ble Supreme Court in Md. Sahabuddin's case (*supra*).

20. Learned SPP submits that in the present case, the petitioner was found carrying two packets, each containing 55 bottles of 'Phensedyl New' (containing Codeine as one of its ingredients) in his checked-in

luggage. The petitioner could not produce any document to justify the possession of the aforesaid 110 bottles of 'Phensedyl New' and therefore, the present case is covered by the judgment of the Hon'ble Supreme Court in Mohd. Sahabuddin's case (*supra*) and furthermore, the entire quantity contained in the aforesaid bottles will have to be calculated for purpose of prosecuting the petitioner under the NDPS Act. The said quantity, according to the learned SPP would be 11000 ml (100 ml x 110) which would be categorised as commercial, as per entry no. 28 in the notification specifying small quantity and commercial quantity of Codeine as 10g and 1kg respectively, and therefore, the rigours of Section 37 of the NDPS Act would apply and the petition for seeking bail should be dismissed.

21. Before we proceed to answer the questions referred to this bench, we feel that the decision of the learned Single Judge of this court in Iqbal Singh *(supra)* needs to be considered. In Iqbal Singh *(supra)*, learned Single Judge was concerned with the bail application filed by the petitioner therein, in a complaint case filed by the Narcotic Control Bureau (NCB) under Section 8 and 21 of the NDPS Act. The recovery in the said case was alleged to be 57 bottles of 'Onerex' cough syrup. The said cough syrup, as in the present case, also contained Codeine Phosphate. The learned Single Judge after examining the provisions of the NDPS Act as well as The Drugs and Cosmetics Act, was of the *prima facie* view that the alleged recovery from the petitioner was of a cough syrup (having codeine as one of its ingredients) which is not a narcotic drug covered under the NDPS Act. The learned Single Judge in Para 16 observed:

> *"16. The product recovered from the petitioner is a cough syrup and not any narcotic drug. Mr Dhaka also pointed out that the said product (cough syrup) is sold openly in the market and is also available online. The fact that the said product also includes miniscule quantity (0.17%) of a prohibited or controlled substances cannot, prima facie, change the nature of the product. In terms of Entry 35 of the list of manufactured drugs (as contained in Govt. of India notifications SO 826(E) dated 14.11.1985., S.O. 40(E) dated 29.01.1993 and S.O. 1431(E) dated 21.06.2011), the product recovered from the petitioner does not fall within the ambit of a manufactured drug as the content of Codeine phosphate is less than 2.5%."*

22. As far as the decision of Hon'ble Supreme Court in Hira Singh *(supra)*, is concerned, it is observed that the learned Single Judge in Iqbal Singh was of the *prima facie* view that the recovered substance in the said case i.e. cough syrup (having codeine as one of its ingredient) would fall outside the scope of definition of the 'manufactured drug' under the NDPS Act and the learned Single Judge in Para 25 has held:

> *"25. Plainly, the quantity of the mixture of a manufactured drug and a neutral substance would require to be considered for the purposes of determining whether the quantity is a commercial quantity or a small quantity for the purposes of the NDPS Act. However, a drug which is manufactured but falls outside the scope of the definition of a 'manufactured drug' under the NDPS Act on account of the component of offending material being below the prescribed threshold, cannot be construed as a manufactured drug by dissecting its ingredients and considering them in isolation."*

23. In view of the foregoing, learned Single Judge in Iqbal Singh (*supra*) has held in Para 27 as under:

> *"27. At this stage, this Court is not required to examine the matter in any further detail. Suffice it to state that the petitioner has presented reasonable grounds for being acquitted in the present case. There is no allegation that the petitioner is involved in any other case."*

24. In view of the above, we are of the considered opinion that the judgment in Iqbal Singh (*supra*) is not contrary to the judgment of the Hon'ble Supreme Court in Hira Singh *(supra)*. It is relevant to point out that the learned Single Judge in Iqbal Singh *(supra*) has merely stated that the determination of the 'commercial quantity' or otherwise would only be relevant in a case where the prosecution establishes that the recovered substance was either a narcotic drug or a psychotropic substance. The learned Single Judge in Iqbal Singh (*supra*) case was of the *prima facie* view that the cough syrup containing Codeine would not fall within the definition of 'manufactured drug' under the NDPS Act in view of the various provisions and circulars referred to in the judgment.

25. The issue whether a cough syrup containing Codeine manufactured by a licensed manufacturer would fall within the definition of 'manufactured drug' under the NDPS Act or not will be relevant to decide question '(c)' referred to this bench.

26. **Section 2(xiv) defines 'narcotic drug'** as:

"means coca leaf, cannabis (hemp), opium, poppy straw and includes all ***manufactured drugs****".*

(emphasis supplied)

Section 2(x) defining the term 'manufacture' reads as under:

"manufacture", in relation to narcotic drugs or psychotropic substances, includes—
(1) all processes other than production by which such drugs or substances may be obtained;
(2) refining of such drugs or substances;
(3) transformation of such drugs or substances; and
(4) making of preparation (otherwise than in a pharmacy on prescription) with or containing such drugs or substances;"

(emphasis supplied)

Section 2(xi) defines "manufactured drug" as follows:

"(a) all coca derivatives, medicinal cannabis, ***opium derivatives*** *and poppy straw concentrate;*
(b) any other narcotic substance or preparation which the Central Government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the Official Gazette, declare to be a manufactured drug;
but does not include any narcotic substance or preparation which the Central Government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the Official Gazette, declare not to be a manufactured drug;"

(emphasis supplied)

The term 'opium derivative' has been defined under Section 2(xvi) as:

"xxx
(c) phenanthrene alkaloids, namely, morphine, ***codeine****, thebaine and their salts;*

xxx"

(emphasis supplied)

27. It is an admitted position that in the present case, the seized substance i.e. 110 bottles of 'Phensedyl New' is a 'preparation' within the meaning of Section 2(xx) of the NDPS Act. Such 'preparation' to be declared as 'manufactured drug' would have to be notified by the Central Government under Section 2(xi)(b) of the NDPS Act. All 'manufactured drugs' are included within the definition of the 'narcotic drug' under Section 2(xiv) of the NDPS Act. In other words, a preparation to be included in the NDPS Act, would at the first instance have to be declared a 'manufactured drug'.

28. At this stage, it is also pertinent to take note of Entry 35 in notification titled "Manufactured Narcotics Drug" (as contained in Government of India Notification No. S.O. 826 (E) dated 14.11.1985 and S.O. 40(E) dated 21.09.1993 and S.O. no. 1431 (E) dated 21.06.2011) issued in exercise of powers conferred by Sub Clause (b) of Clause (xi) of Section 2 of the NDPS Act which pertains to substance Methyl Morphine (commonly known as 'Codeine'). The said entry reads as under:-

"S.O. 826(E). – 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 narcotic substances and preparations to be manufactured drugs, namely:-***
> *xxx*
> *35. Methyl morphine (commonly known as 'Codeine') and Ethyle 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 of not more than 2.5% in undivided preparations and which have been established in Therapeutic practice.*
> *xxx"*

29. Thus, as per the aforesaid notification, if any 'manufactured drug' within the meaning of Section 2(xi)(b) of NDPS Act contains not more than 100 mg of Methyl Morphine, commonly known as Codeine, per dosage unit, and in that drug, Codeine is compounded with one or more ingredients and if in the said drug the concentration of Codeine is not more than 2.5% in undivided preparation, and the drug has been established in therapeutic practice, it will not be a 'preparation' within the meaning of 'manufactured drug' and, therefore it will not to be a 'narcotic drug'.

30. It is also admitted fact that to clarify this position, on 26.10.2005, the Drug Controller of India, has written a letter to the State Drug Controller stating as follows:

> *"As you are aware there are number of Cough preparations like Corex of M/s Pfizer Ltd. 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 10 mg as one of the ingredients. By virtue of the fact that these preparations contain Codeine and it salts they do not fall under the provisions of NDPS Act and Rules of 1985 but they fall under Schedule H of the Drugs and Cosmetics Rules and are governed by the said rules."*

31. In view of the above provisions of the NDPS Act, The Drugs and Cosmetics Act, The Drugs and Cosmetics Rules, 1945 and the aforesaid circular, the learned Single Judge in Iqbal Singh (*supra)* came to a *prima facie* conclusion that 'Onerex' cough syrup containing 0.17% of Codeine was below the prescribed threshold and could not be construed as a 'manufactured drug' by dissecting its ingredients and considering them in isolation.

32. In Mohd. Sahabuddin (*supra*), the Hon'ble Supreme Court was dealing with the case of seizure of 347 cartons with each carton containing 100 bottles of 100 ml of 'Phensedyl' cough syrup and 102 cartons of 100 bottles of 100 ml bottles of 'Recodex' cough syrup which were found concealed, along with other household articles, in a truck. Both the aforesaid cough syrups were pharmaceutical drugs covered under the Drugs and Cosmetics Act and the Rules framed thereunder. Taking note of the notifications dated 14.11.1985 and 29.01.1993 (issued under Section 2(xi)(b) of the NDPS Act), as mentioned hereinabove, the Hon'ble Supreme Court in the aforesaid judgment held as under:

> *"10. It is not in dispute that each 100 ml bottle of Phensedyl cough syrup contained 183.15 to 189.85 mg of codeine phosphate and the each 100 ml bottle of*

Recodex cough syrup contained 182.73 mg of codeine phosphate. When the appellants were not in a position to explain as to whom the supply was meant either for distribution or for any licensed dealer dealing with pharmaceutical products and in the absence of any other valid explanation for effecting the transportation of such a huge quantity of the cough syrup which contained the narcotic substance of codeine phosphate beyond the prescribed limit, the application for grant of bail cannot be considered based on the above submissions made on behalf of the appellants.

xxx

12. As pointed out by us earlier, since the appellants had no documents in their possession to disclose as to for what purpose such a huge quantity of Schedule H drug containing narcotic substance was being transported and that too stealthily, it cannot be simply presumed that such transportation was for therapeutic practice as mentioned in the Notifications dated 14-11-1985 and 29-1-1993. Therefore, if the said requirement meant for therapeutic practice is not satisfied then in the event of the entire 100 ml content of the cough syrup containing the prohibited quantity of codeine phosphate is meant for human consumption, the same would certainly fall within the penal provisions of the NDPS Act calling for appropriate punishment to be inflicted upon the appellants. Therefore, the appellants' failure to establish the specific conditions required to be satisfied under the abovereferred to notifications, the application of the exemption provided under the said notifications in order to consider the appellants' application for bail by the courts below does not arise.

13. As far as the grievance raised on the ground that the appellants were illegally detained beyond 24 hours by the police is concerned, the conclusion of the

High Court having been based on the satisfaction reached by it, we do not find any scope to interfere with the same."

33. Recently, the Hon'ble Supreme Court in State of Punjab vs. Rakesh Kumar (2019) 2 SCC 466, reversed a decision of the Hon'ble High Court of Punjab and Haryana, granting suspension of sentence to the convicts under Section 389 Cr.P.C and held as under:

"10. In the present case, the respondent-accused were found in bulk possession of manufactured drugs without any valid authorisation. The counsel on behalf of the appellant State has extensively stressed that the actions of the respondent-accused amounts to clear violation of Section 8 of the NDPS Act as it clearly prohibits possession of narcotic substances except for medicinal or scientific purposes. In furtherance of the same, the counsel on behalf of the appellant State has put emphasis on the judgment rendered by this Court in Union of India v. Sanjeev V. Deshpande , wherein it was held that : (SCC pp. 12-13, paras 25-26)

"25. In other words, DEALING IN narcotic drugs and psychotropic substances is permissible only when such DEALING is for medical purposes or scientific purposes. Further, the mere fact that the DEALING IN narcotic drugs and psychotropic substances is for a medical or scientific purpose does not by itself lift the embargo created under Section 8(c). Such a dealing must be in the manner and extent provided by the provisions of the Act, Rules or Orders made thereunder. Sections 9 and 10 enable the Central and the State Governments respectively to makerules permitting and regulating variou s aspects contemplated under Section 8(c),

> *of DEALING IN narcotic drugs and psychotropic substances.*
>
> *26. The Act does not contemplate framing of rules for prohibiting the various activities of DEALING IN narcotic drugs and psychotropic substances. Such prohibition is already contained in Section 8(c). It only contemplates of the framing of rules for permitting and regulating any activity of DEALING IN narcotic drugs or psychotropic substances."*
>
> *(emphasis supplied)*
>
> *13. However, we are unable to agree on the conclusion reached by the High Court for reasons stated further. First, we note that Section 80 of the NDPS Act, clearly lays down that application of the Drugs and Cosmetics Act is not barred, and provisions of the NDPS Act can be applicable in addition to that of the provisions of the Drugs and Cosmetics Act. The statute further clarifies that the provisions of the NDPS Act are not in derogation of the Drugs and Cosmetics Act, 1940. This Court in Union of India v. Sanjeev V. Deshpande , has held that : (SCC p. 16, para 35)*
>
> *"35. ... essentially the Drugs and Cosmetics Act, 1940 deals with various operations of manufacture, sale, purchase, etc. of drugs generally whereas Narcotic Drugs and Psychotropic Substances Act, 1985 deals with a more specific class of drugs and, therefore, a special law on the subject. Further, the provisions of the Act operate in addition to the provisions of the 1940 Act."*
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> *(emphasis supplied)"*

34. It is pertinent to note that the aforesaid decision is related to an order passed by the Hon'ble High Court of Punjab and Haryana,

granting suspension of sentence to convicts under the NDPS Act. Some of the said cases in the table which is a part of the aforesaid judgment reflect that some of the respondents therein were convicted for possession of cough syrup containing Codeine Phosphate, while others had been convicted for possession of other narcotic drugs or psychotropic substances.

35. A division bench of the Hon'ble High Court of Allahabad in case titled as Vibhor Rana vs. Union of India, 2021 SCC Online All 908, after analyzing the provisions of the NDPS Act, The Drugs and Cosmetics Act, and the Drugs and Cosmetics Rules, observed as under:

> *"24. The prohibition contained in Section 8 of the Act is applicable to "Narcotic Drugs" and since Phensedyl New Cough Linctus contains Codeine compounded with one other ingredient, namely Chlorpheniramine Maleate and since Phensedyl New Cough Linctus contains merely 10 milligrams per dosage unit of 5 ml, which is not more than 100 milligrams of the drug per dosage unit in undivided preparations and the concentration of Codeine in Phensedyl New Cough Linctus is merely 0.2%, which obviously is not more than 2.5% and which has been established in Therapeutic practice, it is not a "Manufactured Drug" and, therefore, it is not a "Narcotic Drug", the prohibition contained in Section 8 of the Act does not apply to it.*
>
> *25. Phensedyl New Cough Linctus contains Codeine which is mentioned at Serial Number 20 in Schedule H1 appended to the Drugs Rules, 1945 and a note appended to Schedule H1 provides that "Preparations containing the above drug substances and their sales excluding those intended for topical or external use (except opthalmic and ear or nose preparations)*

containing above substances are also covered by this Schedule". Therefore, Phensedyl New Cough Linctus is a drug covered by the Drugs and Cosmetics Act, 1940.

26. To clarify this position, on 26.10.2005 the Drug Controller General of India had written letter to all the State Drugs Controllers stating as follows:—

> *"As you are aware there are number of Cough preparations like Corex of M/s Pfizer Ltd. 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 10 mg as one of the ingredients. By virtue of the fact that these preparations contain Codeine and it salts they do not fall under the provisions of NDPS Act and Rules of 1985 but they fall under Schedule H of the Drugs and Cosmetics 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 prescriptions drug and are to be dispensed on the prescription of a registered Medical Practitioner 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."

27. In March 2009 the Drugs Controller General (India) had issued a letter to the Associated Chambers of Commerce and Industry of India in response to a request for clarification of drug substance Cough Linctus containing codeine Phosphate stating that:—

"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 10 mg 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 prescriptions of a registered Medical

> *Practioner 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 miligrams 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."*

36. The Division Bench of High Court of Allahabad in Vibhor Rana (*supra*), after examining the aforesaid judgment of the Hon'ble Supreme Court in the State of Punjab Vs. Rakesh Kumar (*supra*) has observed:

> *"35. However, whether Phensedyl New Cough Linctus, or any substance containing "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 of not more than 2.5% in undivided preparations and which have been established in Therapeutic practice." falls within the exception to item No. 35 of the Notification dated*

> *14-11-1985 issued by the Government of India containing the list of narcotic drugs and whether it is a "Manufactured drug' and is a "narcotic substance' was neither raised nor adjudicated in this case.*
>
> *xxx*
>
> *38. In both the aforesaid decisions in State of Punjab v. Rakesh Kumar and Hemant Kumar Saini v. Union of India (Supra), the question whether or not the offending substances fell within the definitions of "manufactures drugs" and "narcotic substance" provided in Sections 2 (xi) and 2 (xiv) of the NDPS Act, was not decided. However, in the present case, the composition of the drug has been pleaded specifically and the same has not been disputed by the respondents. It is thus admitted that Phensedyl New Cough Linctus contains Codeine compounded with one other ingredient, namely Chlorpheniramine Maleate and contains merely 10 milligrams per dosage unit of 5 ml, which is not more than 100 milligrams of the drug per dosage unit in undivided preparations and the concentration of Codeine in Phensedyl New Cough Linctus is merely 0.2%, which obviously is not more than 2.5%. and the precise question involved in the case is on the basis of the aforesaid undisputed facts, whether Phensedyl New Cough Linctus falls within the exception mentioned in entry 35 of the Notification dated 14-11-1985 or not and consequently, whether the provisions of the NDPS Act would apply to it or not. Therefore, both the aforesaid judgments are not relevant for deciding the question involved in the present Writ Petition."*

37. It may be noted that in the judgment of Hon'ble Supreme Court in Md. Sahabuddin (*supra*) it had been observed that the twin conditions in Entry 35, as aforesaid mentioned, would be fulfilled only if the recovered substance was "being used for therapeutic practice"

and further observed in Para 11 of the said judgment;

> "*11…Therapeutic practice as per dictionary meaning means "contributing to cure of disease". In other words, the assessment of codeine content on dosage basis can only be made only when the cough syrup is definitely kept or transported which is exclusively meant for its usage for curing a disease and as an action of remedial agent."*

The Division Bench in Vibhor Rana (*supra*) had an occasion to deal with the expression used in the aforesaid Entry 35 viz. "established in Therapeutic Practice" and held as under:

> *"41. The expression "established in therapeutic practice" has not been interpreted in any previous decision. It is a basic rule of interpretation that the words used in the statute should be given there simple and natural meaning and neither any word should be added nor should any word be ignored while interpreting any provision. When the Government has used the expression "established in therapeutic practice" these words cannot be altered so as to read it as "used for therapeutic purposes". The phrase "established in therapeutic practice" apparently means that the compound in question has been established to be a drug in accordance with the therapeutic practices followed for establishment of new drugs. Therefore, the submission of Sri. Ashish Pandey that the drug in question does not fulfil the condition no. (2) of having been "established in therapeutic practice", is without any force."*

38. The aforesaid case of Vibhor Rana (*supra*) was in nature of a writ petition seeking quashing of the complaint case filed by the NCB, pending before the court of Special Judge NDPS Act and in its final conclusion the aforesaid division bench has held as under:

> *"44. In view of the foregoing discussion, we hold that in view of the fact that as per the composition of Phensedyl New Cough Linctus pleaded in the Writ Petitions, the prescription dosage of Phensedyl Cough Syrup is 5 ml and each dosage unit thereof contains 10 mg of Codeine Phosphate IP, besides Chlorpheniramine Maleate I.P., Phensedyl New Cough Linctus contains merely 0.2 % Codeine, and this has not been disputed and rather has been admitted by the learned Counsel for the Respondent NCB that there is no dispute that the drug in question fulfils the first condition for falling within the exception to Entry 35 of the Notification dated 14-11-1985 issued by the Central Government containing the list of Narcotic Drugs, i.e. being "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% in undivided preparations", Phensedyl New Cough Linctus is not a Narcotic Drug and any dealing in this drug would not be subject to the provisions of the NDPS Act. The search and seizure conducted by the NCB Officials in Jaunpur on 17-01-2021 was without any authority of law and so is the complaint filed on 15-07-2021 by the Intelligence Officer, NCB under Sections 8, 21 (c), 22, 25, 29 and 60 (3) of the NDPS Act in the Court of Special Judge, NDPS Act at Jaunpur."*

39. The aforesaid judgments, however, have not considered the scope of Section 9(1)(a)(va) of the NDPS Act which provides as under:

> *"**9. Power of Central Government to permit, control and regulate.-***
>
> *(1) Subject to the provisions of Section 8, the Central Government may, by rules—*

> *(a) permit and regulate—*
>
> *xxx*
>
> *(va) the manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption and use of essential narcotic drugs:*
>
> *Provided that where, in respect of an essential narcotic drug, the State Government has granted licence or permit under the provisions of Section 10 prior to the commencement of the Narcotic Drugs and Psychotropic Substances (Amendment) Act, 2014, such licence or permit shall continue to be valid till the date of its expiry or for a period of twelve months from such commencement, whichever is earlier.*
>
> *xxx"*

40. The aforesaid sub-clause (va) was introduced by the Narcotic Drugs and Psychotropic Substances (Amendment) Act, 2014 (No. 16 2014), which came into effect on 01.05.2014. The said amendment was introduced subsequent to the judgment of Hon'ble Supreme Court in Mohd. Sahabuddin's case (*supra*). A bare reading of the said amended provision shows that the same was introduced in the NDPS Act authorizing the government to permit and regulate the manufacture, possession, transport, import interstate, export interstate, sale, purchase, consumption and use of the **"essential narcotic drugs"**. The term 'essential narcotic drugs' has not been defined in the NDPS Act. However, exercising powers under Section 9(1)(a)(va) of the NDPS Act, the Central Government vide notification dated 05.05.2015 (w.e.f. 05.05.2015) added Chapter –VA to The Narcotic Drugs and Psychotropic Substances Rules 1985 (hereinafter "NDPS Rules").

Rule 52A of the said Chapter provides as under:

> ***"52A. Possession of essential narcotic drug****.—(1) No person shall possess any essential narcotic drug otherwise than in accordance with the provisions of these rules.*
>
> *(2) Any person may possess an essential narcotic drug in such quantity as has been at one time sold or dispensed for his use in accordance with the provisions of these rules.*
>
> *(3) A registered medical practitioner may possess essential narcotic drug, for use in his practice but not for sale or distribution, not more than the quantity mentioned in the Table below, namely—*

TABLE

Sl. No.	*Name of the essential narcotic drug*	*Quantity*
(1)	*(2)*	*(3)*
1.	*Morphine and its salts and all preparations containing more than 0.2 per cent of Morphine*	*500 Milligrammes*
2.	***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 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5% in undivided***	***2000 Milligrammes***

	preparations and which have been established in therapeutic practice	
3.	*Dihydroxy Codeinone (commonly known as Oxy-codone and Dihydroxycodeinone), its salts (such as Eucodal Boncodal Dinarcon Hydrolaudin, Nucodan, Percodan, Scophedal, Tebodol and the like), its esters and the salts of its ester and preparation, admixture, extracts or other substances containing any of these drugs*	*250 Milligrammes*
4.	*Dihydrocodeinone (commonly known as Hydrocodone), its salts (such as Dicodide, Codinovo, Diconone, Hycodan, Multacodin, Nyodide, Ydroced and the like) and its esters and salts of its ester, and preparation, admixture, extracts or other substances containing any of these drugs*	*320 Milligrammes*
5.	*1-phenethyl-4-N-propionylanilino-piperidine (the international non-proprietary name of which is Fentanyl) and its salts and preparations, admixture, extracts or other substances containing any of these drugs*	*Two transdermal patches one each of 12.5 microgram per hour and 25 microgram per hour:*

> *Provided that the Controller of Drugs or any other officer authorised in this behalf by him may by special order authorise, in Form 3-B, any such practitioner to possess the aforesaid drugs in quantity larger than as specified in the above Table:*
>
> *Provided further that such authorisation may be granted or renewed, for a period not exceeding three years at a time.*
>
> *Explanation.—The expression "for use in his practice" covers only the actual direct administration of the drugs to a patient under the care of the registered medical practitioner in accordance with established medical standards and practices.*
>
> *xxx"*
>
> (emphasis supplied)

41. Since, during the course of the hearing, the aforesaid provision was not brought to the notice of the court, the matter was listed for clarification. Subsequently, learned counsel appearing on behalf of the petitioner placed reliance on the judgment rendered by the division bench of Hon'ble High Court of Allahabad in Vibhor Rana (*supra*). He further submitted that Rule 66 of the NDPS Rules would be applicable in the facts and circumstances of the present case, and not Rule 52A. Rule 66 of the NDPS Rules provides as under:

> *"66. Possession, etc., of psychotropic substances.—(1) No person shall possess any psychotropic substance for any of the purposes covered under 1945 rules, unless he is lawfully authorized to possess such substance for any of the said purposes under these rules: Provided that possession of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in Chapter VII-A.*

> *(2) Notwithstanding anything contained in sub-rule (1), any research institution, or a hospital or dispensary maintained or supported by the Government or local body or by charity or voluntary subscription, which is not authorised to possess any psychotropic substance under the 1945 Rules, or any person who is not so authorised under the 1945 Rules, may possess a reasonable quantity of such substance as may be necessary for their genuine scientific requirements or genuine medical requirements, or both for such period as is deemed necessary by the said research institution or, as the case may be, the said hospital or dispensary or person: Provided that where such psychotropic substance is in possession of an individual for his personal medical use the quantity thereof shall not exceed one hundred dosage units at a time:*
>
> *Provided further that an individual may possess the quantity of exceeding one hundred dosage units at a time but not exceeding three hundred dosage units at a time] for his personal long term medical use if specifically prescribed by a Registered Medical Practitioner.*
>
> *(3) The research institution, hospital and dispensary referred to in sub-rule (2) shall maintain proper accounts and records in relation to the purchase and consumption of the psychotropic substance in their possession.*

A bare perusal of the aforesaid rule clearly shows that the reliance placed on the same by learned counsel appearing on behalf of the petitioner is misplaced. The aforesaid Rule 66 relates to psychotropic substances and therefore, is not applicable to 'codeine' which is admittedly a 'narcotic drug' under the NDPS Act.

42. As mentioned earlier, the term **'essential narcotic drugs'** has

not been defined under the NDPS Act but the table in Rule 52A, Sub-Rule (3), at serial no. 2, under the title "Name of essential narcotic drug" gives a description of Methyl Morphine (commonly known as 'Codeine'), which is an exact verbatim copy of Entry no. 35 in notification titled "Manufactured Narcotics Drug" (as contained in Government of India Notification No. S.O. 826 (E) dated 14.11.1985 and S.O. 40(E) dated 21.09.1993 and S.O. no. 1431 (E) dated 21.06.2011). A combined reading of Rule 52A of The NDPS Rules and Entry no. 35, in the aforementioned notification, would demonstrate that the exception carved out in Entry no. 35, of the aforesaid notifications, with respect to codeine, has been further qualified by way of its inclusion under the category of **'essential narcotic drug'** under Section 9(1)(a)(va) of the NDPS Act 1985. In our considered opinion, Rule 52A further regulates the manner of possession and other related activities enumerated therein, with respect to substances/preparations covered under the aforesaid Entry 35.

43. Section 21 of the NDPS Act provides for prosecution for contravention of any of the provision of the NDPS Act or any Rule made thereunder. Needless to say that Rule 52A clearly prohibits any person from possessing any **'essential narcotic drug'** otherwise than in accordance with the provisions of the rules made thereunder. The amended provision i.e. Section 9(1)(a)(va) of the NDPS Act and the rules made thereunder clearly and unequivocally declare that any substance covered under the description given in the Table to Rule 52A(3) would be considered

as an **'essential narcotic drug'**, even if the said substance is otherwise covered under The Drugs and Cosmetic Act including cough syrup containing codeine phosphate.

44. The aforesaid interpretation is supported by a judgment rendered by the Hon'ble Supreme Court in Union of India and Anr. vs. Sanjeev V. Deshpande (2014) 13 SCC 1, wherein it was held as follows:

> *"25. In other words, DEALING IN narcotic drugs and psychotropic substances is permissible only when such DEALING is for medical purposes or scientific purposes.* ***Further, the mere fact that the DEALING IN narcotic drugs and psychotropic substances is for a medical or scientific purpose does not by itself lift the embargo created under Section 8(c). Such a dealing must be in the manner and extent provided by the provisions of the Act, Rules or Orders made thereunder. Sections 9 and 10 enable the Central and the State Governments respectively to make rules permitting and regulating various aspects*** *(contemplated under Section 8(c), of DEALING IN narcotic drugs and psychotropic substances.*
>
> *26. The Act does not contemplate framing of rules for prohibiting the various activities of DEALING IN narcotic drugs and psychotropic substances. Such prohibition is already contained in Section 8(c). It only contemplates of the framing of Rules for permitting and regulating any activity of DEALING IN narcotic drugs or psychotropic substances.*
>
> (emphasis supplied)

45. The aforesaid amended provisions of the NDPS Act and the Rules made thereunder were not brought to the notice of the learned Single Judge of this court in Iqbal Singh's case (*supra*) as

well as to the notice of the division bench of the Hon'ble Allahabad High Court in Vibhor Rana's case (*supra*).

46. In view of the foregoing analysis of various provision of the NDPS Act, NDPS Rules, The Drugs and Cosmetics Act and the Drugs and Cosmetics Rules and the judgments referred to, we answer the reference in the following terms:

Question - "(c) whether Note 4 of the S.O. 1055 (E) dated 19th October, 2001 published in the Gazette of India,. Extra., Pt.II, Sec3 (ii) dated 19th October 2001, as amended on 18.11.2009, should be made applicable to cough syrups containing miniscule percentage of Codeine since it has medicinal value and is also easily available?"

Ans: If the contraband recovered in a particular case is covered by Rule 52A of the NDPS Rules made under Section 9(1)(a)(va) of the NDPS Act, then violation of the said Rules would be punishable under the NDPS Act. In that situation, Note 4 of the S.O. 1055 (E) dated 19th October, 2001 would be applicable to such substances including cough syrup.

47. As far as the questions (a) and (b) referred to us by the learned Single Judge are concerned, the same are squarely covered by the judgment of the Hon'ble Supreme Court in Hira Singh (supra) wherein the Hon'ble Supreme Court was disposing of a reference as well as a challenge to the validity of notification bearing no. S.O. 2941(E) dated 18.11.2009, adding 'Note 4' to the notification bearing no. S.O. 1055(E) dated 19.10.2001. The

Hon'ble Supreme Court in Hira Singh (supra) has clearly held as under:

> *"12.2. In case of seizure of mixture of narcotic drugs or psychotropic substances with one or more neutral substance(s), the quantity of neutral substance(s) is not to be excluded and to be taken into consideration along with actual content by weight of the offending drug, while determining the "small or commercial quantity" of the narcotic drugs or psychotropic substances."*

48. In view of the aforesaid decision, the questions (a) and (b) referred to us are answered as follows:

Question - "(a) whether in cases specifically related to manufactured drug with a miniscule percentage of a narcotic substance, the weight of the neutral substance ought to be ignored while determining the nature of the quantity seized i.e. small, commercial or in between?"

Ans: If the contraband seized falls within the provisions of NDPS Act, the weight of the neutral substance would not be ignored while determining the nature of the quantity seized, whether small quantity, commercial quantity or in between.

Question - "(b) whether Note 4 of the S.O. 1055 (E) dated 19th October, 2001 published in the Gazette of India, Extra., Pt.II, Sec3 (ii) dated 19th October 2001, as amended on 18.11.2009, should be held inapplicable to manufactured drug which contain a miniscule percentage of a narcotic drug?"

Ans: If the alleged contraband seized falls within the definition of 'manufactured drug' under Section 2(xi) of the NDPS Act, then the

entire notification including the aforesaid 'Note 4' will be applicable.

49. Having answered the questions referred to us, this matter may be placed before the appropriate bench for considering the question of grant of bail.

AMIT SHARMA
JUDGE

SIDDHARTH MRIDUL
JUDGE

September 16th, 2022/hb