***IN THE HIGH COURT OF PUNJAB AND HARYANA AT CHANDIGARH.***

***Crl. Misc. No.M-37530 of 2015***
Date of Decision: 18.11.2015

Dr. Rajinder Singla ....Petitioner

Versus

State of Punjab ....Respondent

***BEFORE :- HON'BLE MRS. JUSTICE DAYA CHAUDHARY***

1. **Whether reporters of local newspapers may be allowed to see the judgment ? (Yes/No)**
2. **To be referred to reporters or not ? (Yes/No)**
3. **Whether the judgment should be reported in the Digest ? (Yes/No)**

Present:- Mr. Vikram Chaudhari, Sr. Advocate
with Ms. Isha Goyal, Advocate
for the petitioner.

Mr. Rupam Aggarwal, D.A.G., Punjab
for the respondent-State.

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***DAYA CHAUDHARY, J.***

This petition has been filed under Section 439 of the Code of Criminal Procedure for release of the petitioner on regular bail during pendency of the trial in case FIR No.59 dated 03.08.2015 registered under Section 22 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (here-in-after referred to as the `NDPS Act') at Police Station Banur, District Patiala.

Learned counsel for the petitioner submits that the petitioner has falsely been implicated in the case, whereas, no offence under Section 22 of the NDPS Act is made out against him. The petitioner, being doctor by profession, was entitled/competent to possess medicines including *Buprenorphine*, which has been alleged to be recovered from him. The

provisions of NDPS Act are not attracted as there is no bar to keep the medicines. As per allegations in the FIR, the petitioner was apprehended while driving his vehicle and from the search of his vehicle, various medicines including *Buprenorphine* were recovered. An application was also moved by the petitioner before the Judicial Magistrate Ist Class, Rajpura for getting his statement recorded under Section 164 of the Cr.P.C but the same was dismissed by passing cryptic mechanical order on the same date i.e 04.08.2015. Learned counsel further submits that as per Rule 64, 65-A and 66 of the NDPS Rules, 1985 (here-in-after referred to as `the Rules'), there was no bar in keeping medicines being a doctor. Learned counsel also submits that a registered Medical Practitioner is exempted from all provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and Rules thereunder, except the requirement of purchasing the drug from a licensed dealer or manufacturer. The petitioner has been complying with the conditions as mentioned under the Rules. Learned counsel also submits that there is no provision of law that *Buprenorphine* therapy can be given only to indoor patients and not on OPD basis and the petitioner's claim of bail has been rejected only on this ground. There is no legal provision which bars the petitioner to keep medicines with him. Moreover, *Buprenorphine tablets* are being sold in the hospital as well as by the chemists in various Chemist Shops but just to falsely implicate the petitioner, the present FIR has been registered. As per provisions of NDPS Act, 1985 or Rules or the Drugs and Cosmetics Act, 1940 and Rules framed thereunder, there is no requirement of the license for the Registered Medical Practitioners. The petitioner is in custody since 03.08.2015. Learned counsel for the petitioner also submits that ***CWP No.1361 of 2015*** was filed by one Dr. Ashwin Mohan before this Court under similar circumstances and his warrants of arrest were stayed. The

said petition is still pending and the interim order is also continuing.

Learned counsel for the respondent-State opposes the submissions made by learned counsel for the petitioner on the ground that the bail of the petitioner has rightly been rejected by the lower Court as he was entitled only to do practice and to prescribe medicines and being a doctor, he cannot posses huge quantity of medicines.

Heard the arguments of learned counsel for the parties and have also perused the documents available on the file.

The FIR, in dispute, was registered against the petitioner on 03.08.2015. As per allegations in the FIR, a secret information was received by ASI Amrik Singh to the effect that the accused was selling intoxicant medicines to the drug addicts after getting the same at lower rate. The accused-petitioner was apprehended and 38 boxes of *Nabuse-LS, 30 boxes of Nabuse-0.4 mg, 45 boxes of Buproex-N Lite and 18 boxes of Buproex-I* were recovered from him. However, on the basis of said recovery, the FIR, in question was registered against the petitioner.

As per case of the prosecution, after considering the total quantity, *Buprenorphine hydrochloride* found in parcles no.1, 2, 3 and 4 was of commercial quantity.

Learned counsel for the petitioner has argued that the provisions of NDPS Act are not applicable and the petitioner has falsely been implicated in the case. The doctor is competent/entitled to stock medicines for doing practice.

Now the question for consideration is as to whether a criminal case can be registered against a doctor under the NDPS Act, 1985 or not. The bail application filed by the petitioner was dismissed on the ground that the petitioner, being a doctor, he can only prescribe medicines but cannot stock such huge quantity of the medicines. It is to be decided as to whether

*Buprenorphine Hydrochloride I.P. injections* are covered under the definition of psychotropic substance under the NDPS Act. If they are not to be regarded as psychotropic substances then no offence under the NDPS Act would be made out. In such a situation, the petitioner becomes entitled to be enlarged on bail. In case, it is held that being a doctor, he cannot keep said medicine, the provisions of NDPS Act would be attracted or not. The question is also for consideration as to whether merely by keeping the possession of *Buprenorphine Hydrochloride* would attract the punishment under NDPS Act. The provisions with regard to *Buprenorphine Hydrochloride* in Drugs and Cosmetics Act, 1940 (hereinafter called as the "D and C Act"), the Drugs and Cosmetics Rules, 1945 (hereinafter called as the "D and C Rules"), the Narcotic Drugs and Psychotropic Substances Act and the NDPS Rules. Rule 65 of the D and C Rules prescribes the general conditions for licences in Forms 20, 20A, 20B, 20F, 20G, 21 and 21B. Sub-rule (3)(1) of Rule 65 stipulates that the supply of any drug, other than those specified in Schedule X, on the prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of entry in the register shall be entered on the prescription. Several particulars are required to be entered in the Register such as, serial number of the entry, the date of supply, the name and address of the prescriber etc. In case of a drug specified in Schedule `H', it is also necessary to record the name of the manufacturer of the drug, its batch number and the date of expiry, if any.

Rule 97 of the D and C Rules contains stipulations with regard to the labelling of medicines. It specifically provides that the container of a medicine for internal use shall, if it contains a substance specified in Schedule `H', be labelled with the symbol Rx conspicuously displayed on

the top left corner of the label and shall also be labelled with the following words :-

> "Schedule `H' drug" Warning " to be sold by retail on the prescription of a Registered Medical Practitioner only."

This is so provided in Rule 97(1)(b) of the D and C Rules. However, if the substance contained in the container is one specified in Schedule `H' and also comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, it is required to be labelled with the symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label, and be also labelled with the following words :-

> "Schedule H drug" "Warning " To be sold by retail on the prescription of a Registered Medical Practitioner only."

This is so provided in Rule 97(1)(c) of the D and C Rules. It may also mention Rule 104 of the said Rules which provides that the letters "IP" and recognised abbreviations of the pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the Rules. An examination of Schedule `H' of the D and C Rules makes it clear that Buprenorphine Hydrochloride is listed therein as a "Prescription Drug." A4. From an analysis of the above provisions, it is clear that Buprenorphine Hydrochloride, if it conforms to the standards prescribed under the Indian Pharmacopoeia, is to be known as Buprenorphine Hydrochloride I.P. It is further clear that Buprenorphine Hydrochloride is a prescription drug specified in Schedule `H' and is to be sold by retail only on the prescription of a Registered Medical Practitioner. The stipulation with regard to the entries made in the Register as prescribed under Rule 65 have also to be complied with by the retailer

making the sales. It is also to be noted that a reading of Rule 97(1)(c) clearly indicates that it is quite possible that a drug falling within the meaning of the Drugs and Cosmetics Act, 1940 and the D and C Rules and particularly one falling under Schedule `H' can also fall within the purview of the Narcotic Drugs and Psychotropic Substances Act. If it is so, the manufacturer is duty bound to place the symbol NRx in red on the top left corner of the label.

Section 2(xxiii) defines “Psychotropic substances” as under :-

> “(xxiii) “psychotropic substance” means any substance, natural or synthetic or any natural material or any salt or preparation of such substance or materials included in the list of psychotropic substances specified in the Schedule.”

A plain reading of the above definition makes it clear that a psychotropic substance could be any substance, natural or synthetic, or any natural material or `any salt or preparation' of such substance or materials included in the list of psychotropic substances specified in the Schedule. For this purpose, a reference to the Schedule becomes necessary. The Schedule to the Narcotic Drugs And Psychotropic Substances Act gives a list of phychotropic substances. Entry Nos.92 and 110 are relevant and they read as under :-

| Sl. No. | International Non-Proprietary names | Other Non-Proprietary names | Chemical Name |
|---|---|---|---|
| 92 | Buprenorphine | 21-cyclopropyl-7 (a) [(S)-1 hydroxy-1, 2.2-trimethyl propyl]-6, 14-endo, ethano-6, 7, 8, 14-tetrahydrooripavine. | |
| 110 | Salts and Preparations of above | | |

Entry No.110 was originally entry No.77. It was re-numbered as Entry No.106 in 1992 and as Entry No.110 with effect from 11th June, 2003. From a conjoint reading of Section 2(xxiii) and the aforesaid Entry

Nos.92 and 110 of the Schedule to the Narcotic Drugs and Psychotropic Substances Act it becomes clear that Buprenorphine Hydrochloride is not mentioned by name in the schedule and that is only Buprenorphine which has been listed as a psychotropic substance.

The next question to be answered is whether Buprenorphine Hydrochloride is a `salt or preparation' of Buprenorphine which is a psychotropic substance specified in the Schedule to the Narcotic Drugs And Psychotropic Substances Act. The word `preparation' is defined under the Narcotic Drugs And Psychotropic Substances Act in Section 2(xx) thereof as under :-

> "2(xx) "Preparation" in relation to a narcotic drug or psychotropic substance, means any one or more such drugs or substances in dosage form or any solution or mixture, in whatever physical state, containing one or more such drugs or substances:
>
> If Buprenorphine Hydrochloride were to be a preparation of Buprenorphine, in terms of the aforesaid definition, it would have to be in dosage form or any solution or mixture, in whatever physical state, containing Buprenorphine. Buprenorphine Hydrochloride, as admitted by all the counsel appearing in the matter, is neither a solution nor a mixture of Buprenorphine. In fact, it is an entirely different compound. Furthermore, it could also not be regarded as Buprenorphine is dosage form. Therefore, it is clear that Buprenorphine Hydrochloride cannot be regarded as a "preparation" of Buprenorphine. Consequently, I am left with the only alternative consideration and that is- -whether Buprenorphine Hydrochloride is a "salt" of Buprenophine? If it is, then it would be a psychotropic substance within the meaning of Section 2(xxiii) as well as Entry 110 read with Entry 92 of the Schedule to the NDPS Act. For this purpose I had, during the course of hearing, sought clarifications from the Chemical Examiner with regard to the nature of Buprenorphine Hydrochloride. The letter dated 8th January,

2005 written by the Chemical Examiner Grade-II, Customs Laboratories, Customs House, Kandla, addressed to Mr Satish Aggarwal, Senior Special Public Prosecutor was placed before me. In that letter, it has been stated that Buprenorphine Hydrochloride is a salt of Buprenorphine. It was further indicated that Buprenorphine and its salts including Buprenorphine Hydrochloride give a positive test for Buprenorphine on testing. A similar letter by the same Chemical Examiner was written on 3rd of February, 2005 where he has again indicated as under:-

"In my opinion Buprenorphine Hydrochloride may be said to be a salt of Buprenorphine".

So, it is clear that buprenorphine hydrochloride is a psychotropic substance within the meaning of the NDPS Act. But, would that in itself make the possession, sale or transportation of buprenorphine hydrochloride injections an offence under the NDPS Act, punishable under section 22 thereof? The answer is in the negative. In the context of section 21 of the NDPS Act which is an analogous provision in respect of "narcotic drugs", the Supreme Court, in the case of ***Sajan Abraham v. State of Kerala (2004) 4 SCC 441*** held :-

> “7. It is thus apparent that what is made punishable under Section 21 is possession, sale, purchase, etc. of the drugs and preparations mentioned therein in contravention of any provision of the Act or any rule or order made or condition of license granted there under. Obviously, therefore, if any rule permits a person to possess any psychotropic substance within the limits specified under the rule and subject to such conditions as the rule may prescribe, such a person cannot be held guilty of the offence under Section 21 of the Act if it is shown that his possession is not in contravention of such rule."

This would apply equally to the offence punishable under section 22 of the NDPS Act in relation to psychotropic substances. This is

clear as, in the case of ***Ouseph v. State of Kerala: : 2004(4) SCC 446*** , the Supreme Court had observed that [at page 447]:-

> "If it is a psychotropic substance, possession of it would become an offence only if it was in contravention of the Rules prescribed."

And, in ***Hussain v. State of Kerala: (2000) 8 SCC 139***, the Supreme Court had already held that:-"If it was "psychotropic substance" possession of the same would amount to an offence only if it was in contravention of Section 8 of the Act. That section shows that no person shall possess any psychotropic substance except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the Rules or orders made there under."

Therefore, an examination of section 8 of the NDPS Act and the provisions of Chapter VII of the NDPS Rules is called for. Firstly, Section 8 of the NDPS Act reads as under:-

> "8. Prohibition of certain operations.-- No person shall--
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> (a) cultivate any coca plant or gather any portion of coca plant; or
>
> (b) cultivate the opium poppy or any cannabis plant; or
>
> (c) produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import Interstate, export Interstate, import into India, export from India or transship any narcotic drug or psychotropic substance, except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the rules or orders made there under and in a case where any such provision, imposes any requirement by way of license, permit or authorisation also in accordance with the terms and conditions of such license, permit or authorisation:
>
> Provided that, and subject to the other provisions of this Act and the rules made there under, the prohibition against the cultivation of the cannabis plant for the production of ganja or

> the production, possession, use, consumption, purchase, sale, transport, warehousing, import Interstate and export Interstate of ganja for any purpose other than medicinal and scientific purpose shall take effect only from the date which the Central Government may, by notification in the Official Gazette, specified in this behalf.
>
> Provided further that nothing in this section shall apply to the export of poppy straw for decorative purposes"

Section 8(c), which is relevant for the purpose of this case as it deals with psychotropic substances, prohibits the manufacture, possession, sale, use etc., of any psychotropic substance "except for medical or scientific purposes and in the manner and to the extent" provided by the provisions of the NDPS Act or NDPS Rules or orders made there under. This means that while there is a general prohibition against the manufacture, possession, sale, use etc., of a psychotropic substance, if the same is a medicine and is to be used for a medical purpose then the manner and extent of its manufacture, possession, sale, use shall be as provided in the NDPS Act or NDPS Rules or orders made there under. It must remember that buprenorphine hydrochloride I.P. is a Schedule H Drug within the meaning of the D and C Act and Rules. Its manufacture, sale etc., is regulated by the D and C Act and D and C Rules. Coming back to the NDPS Act, I find that in the case of a medication, which also happens to be a psychotropic substance within the meaning of the NDPS Act, its "extent and manner" of use etc., would be governed by the other provisions of the NDPS Act or NDPS Rules.

Section 9 of the NDPS Act empowers the Central Government to permit, control and regulate, inter alia, the manufacture, possession, sale, transportation of psychotropic substances. The NDPS Rules have been formulated by the Central Government in exercise of that power. Chapter VII of the NDPS Rules deals with "Psychotropic Substances".

Rules 64 to 67 fall under this Chapter VII. Rule 64 prescribes the general prohibition. It provides that -- "No person shall manufacture, possess, transport, import inter-state, export inter-state, sell, purchase, consume or use any of the psychotropic substances specified in Schedule I." It is to be noted that this "Schedule I" is different to the Schedule to the NDPS Act. This Schedule I is appended to the NDPS Rules and is in two parts - (I) Narcotic Drugs and (II) Psychotropic Substances. Here it is concerned with psychotropic substances. There is a list of 33 specific psychotropic substances with entry no. 34 being "Salts and preparations of above". It is significant to note that neither buprenorphine hydrochloride nor buprenorphine find mention in this list. This clearly means that Buprenorphine Hydrochloride is not included in Schedule I to the NDPS Rules and therefore the general prohibition contained in Rule 64 of the NDPS Rules does not apply to it . Consequently, rules 65 to 67, which also have reference to psychotropic substances specified in the said Schedule I, would also not be applicable in respect of Buprenorphine Hydrochoride 3. In this connection, it is pertinent to point out that there are several psychotropic substances which find place both in the Schedule to the NDPS Act and in Schedule I to the NDPS Rules. For example: Methaqualone 4, Delorazepam 5, Ketazolam 6, Loprzolam 7, Pipradrol 8, Tetrazepam 9. At the same time, there are others like Buprenorphine 10, Amphetamine 11, Bromazepam 12, Lorazepam 13, Phenobarbital 14 and Pemoline 15 which, though specified in the Schedule to the NDPS Act, do not find mention in Schedule to the NDPS Rules. Clearly, by conscious design, all psychotropic substances mentioned in the Schedule to the NDPS Act have not been listed in Schedule I to the Rules. The prohibition contained in Rule 64 of the NDPS Rules applies only to those psychotropic substances which are specified in Schedule I to the NDPS Rules. In other

words, the prohibition of Rule 64 of the NDPS Rules is not applicable to those psychotropic substances, which, although they are listed in the Schedule to the NDPS Act, are not part of the listed psychotropic substances in Schedule I to the NDPS Rules. It may be mentioned here that the Supreme Court, in the afore-mentioned decisions, was not called upon to examine this aspect of the matter, namely, whether Rule 66 of the NPS Rules applied to all psychotropic substances or only those specified in Schedule I to the NDPS Rules. It is, therefore, open to this Court to consider and decide this aspect of the matter.

Rule 65(1), inter alia, provides that the manufacture of any psychotropic substance other than those specified in Schedule I shall be in accordance with the conditions of license granted under the D and C Rules and D and C Act. In other words, insofar as the psychotropic substances not mentioned in Schedule I to the NDPS Rules but mentioned in the Schedule to the NDPS Act are concerned, their manufacture shall be governed by the D and C Act and Rules and not by the NDPS Act or NDPS Rules. Rule 66 relates to possession etc., of psychotropic substances. Sub-Rule (1) thereof provides that no person shall possess "any psychotropic substance" for any of the purposes covered by the D and C Rules, unless he is lawfully authorised to possess such substance for any of the said purposes under the NDPS Rules. The expression "any psychotropic substance" obviously has reference to those listed in Schedule I to the NDPS Rules. Rule 64 is the governing rule in Chapter VII of the NDPS Rules. When a psychotropic substance des not find mention in Schedule I to the NDPS Rules, the prohibition qua possession contained in Rule 64 does not apply. That being the case, in respect of such a psychotropic substance, Rule 66 would also not apply as it has reference to only those psychotropic substances which are included in Schedule I to

the NDPS Rules. Rule 67 of the NDPS Rules relates to transport of psychotropic substances. It is expressly subject to the provisions of Rule 64 and clearly has reference to the transport, import inter-state or export inter-state of those psychotropic substances which are included in Schedule I to the NDPS Rules. The rule would have no applicability in respect of those psychotropic substances which are not to be found in Schedule I to the NDPS Rule. Clearly, then, inasmuch as Buprenorphine Hydrochloride is not included in Schedule I to the NDPS Rules, its manufacture, possession, sale, transport would neither be prohibited nor regulated by the NDPS Rules and consequently by the NDPS Act. It being Schedule H drug would fall within the rigours of the D and C Act and Rules.

*Buprenorphine Hydrochloride I.P.* is also a medication and is used as a pain reliever. Recently, it is also being used to treat opiate addiction (such as addiction to heroin). It has legitimate uses as an analgesic and for de-addiction. However, it is also capable of misuser being a psychotropic substance. Perhaps because of this reason, it was left out of Schedule I to the Narcotic Drugs And Psychotropic Substances Act but is very much regulated under the D and C Act and Rules.

As indicated above, Buprenorphine Hydrochloride is a Schedule H drug under the D and C Act and Rules and, though it is a psychotropic substance under the Narcotic Drugs And Psychotropic Substances Act, it is not included in Schedule I to the NDPS Rules. That being the case, its manufacture, possession of sale is not prohibited. As such, there is no contravention of the provisions of the NDPS Rules. Consequently, the offence under Section 8 of the Narcotic Drugs And Psychotropic Substances Act is not made out. Obviously, punishment under Section 22 of the Narcotic Drugs And Psychotropic Substances Act is also not attracted.

Accordingly in these circumstances no offence under the Narcotic Drugs And Psychotropic Substances Act is made out, the petitioner would be entitled to bail. Accordingly, he is directed to be released on bail on furnishing a personal bond in the sum of ₹ 50,000/- with one surety of the like amount to the satisfaction of the concerned trial Court.

(DAYA CHAUDHARY)
JUDGE

18.11.2015
**gurpreet**