

IN THE HIGH COURT OF JUDICATURE AT PATNA

Civil Writ Jurisdiction Case No.23771 of 2012

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Lallan Kumar, son of Late Narmadeshwar Singh, resident of Village- Badpur,
Police Station- Marachi, District- Patna.

.... Petitioner/s

Versus

1. Chairman, Pharmacy Council of India, Combined Council's Building Kotla Road Aiwan-E-Ghalib Marg, New Delhi.
2. The State of Bihar through its Principal Secretary, Department of Health, Government of Bihar, New Secretariat, Patna.
3. The Drug Controller, Government of Bihar, New Secretariat, Patna.
4. The Union of India through its Secretary, Health, Government of India, Central Secretariat, New Delhi.

.... Respondent/s

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Appearance :

For the Petitioner : Mr. Binod Kumar Singh, Advocate.
For Respondent No. 1 : Mr. S.D. Sanjay, Sr. Advocate.
For Respondent No. 4 : Mrs. Kanak Verma, C.G.C.

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CORAM: HONOURABLE THE ACTING CHIEF JUSTICE

and

HONOURABLE MR. JUSTICE VIKASH JAIN

C.A.V. JUDGMENT

(Per: HONOURABLE THE ACTING CHIEF JUSTICE)

Date: 16-12-2016

The petitioner has challenged Clause 3 of Forms 20 and
21 published in exercise of powers conferred under Rule 61(1) of the



Drugs and Cosmetics Rules, 1945 (hereinafter referred to as “the Rules”) which makes it mandatory to disclose the name(s) of qualified person(s) in-charge.

2. The challenge in the present writ application is on the ground that the petitioner is a retail seller of Allopathic medicine manufactured by the licensed manufacturers under the provisions of Drugs and Cosmetics Act, 1940 (hereinafter referred to as “the Act”) and the rules framed there-under. The petitioner asserts that he sells the medicines received from the manufacturers of Allopathic medicines in the same packing without compounding, mixing or dispensing of medicines by raw hands. Since the medicines are prescribed by the registered medical practitioners with patent names, therefore, there is no requirement of a licensed Pharmacist to dispense the medicines.

3. On the other hand, the stand of the Pharmacy Council of India is that the role of a Pharmacist is to ensure that the patient’s drug therapy is appropriately indicated, the most effective, the safest possible and convenient for the patient. The role of the Pharmacist has become even more important as he is the common point of contact between the patient and doctor and is trained to play a key role both in disease prevention and drug safety. New drug discovery/research has led to introduction of new drug molecules and



novel drug delivery systems. The prescribing pattern has changed. Multi drug regiment is the way of treatment leading to lot of cases of not only drug-drug interactions and adverse drug reactions but also drug induced diseases putting the life of patient at risk. It is, thus, contended that the drugs cannot be sold in terms of Section 42 of the Pharmacy Act other than by a registered Pharmacist. Reliance is placed on a Full Bench judgment of the Allahabad High Court in Civil Misc. Writ Petition No. 981 of 1994 (Ramesh Giri, Proprietor, M/s Goswami Medical Stores Vs. State of U.P. and others) decided on 29th of January, 1996 wherein identical issue raised has been decided and it has been held that the drugs cannot be permitted to be sold by a person other than the Pharmacist.

4. Some of the relevant clauses of Drugs and Cosmetics Act, 1940 reads as under:-

“18. Prohibition of manufacture and sale of certain dugs and cosmetics.- From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf-

(a) xx xx xx

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a license issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:



Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.”

Rule 61 of the Rules reads as under:-

“61. Forms of licenses to sell drugs.-(1) A license to sell, stock, exhibit or offer for sale or distribute drugs other than those specified in Schedules C, C(1) and X and by retail on restricted license or by wholesale, shall be issued in Form 20, Form 20-A or Form 20-B, as the case may be:

Provided that a license in Form 20-A shall be valid for only such drugs as are specified in the license.

(2) A license to sell, stock, exhibit or offer for sale or distribute drugs specified in Schedules C and C(1) excluding those specified in Schedule X, by retail on restricted license or by wholesale shall be issued in Form 21, Form 21-A or Form 21-B, as the case may be:

Provided that a license in Form 21-A shall not be granted for drugs specified in Schedule C and shall be valid for only such Schedule C(1) drugs as are specified in the license.

(3) A license to sell, stock, exhibit or offer for sale or distribute drugs specified in Schedule X by retail or by wholesale shall be issued in Form 20-F or Form 20-G as the case may be.”

Form 20 is reproduced as under:-

FORM 20
[See rule 61 (1)]

[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE]

DRUGS BY RETAIL OTHER THAN THOSE SPECIFIED IN [SCHEDULES C, C(1) AND X]

1.is hereby licensed to sell, stock or exhibit or offer for sale or distribute by retail drugs other than those specified in Schedules C,C (1) and X of the Drugs and Cosmetics Rules 1945, *and to operate a pharmacy on the premises situated at..... subject to the



conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder.

xxx

xxx

xxx

xxx

*Delete if not applicable.

Section 42 of the Pharmacy Act is reproduced hereunder:-

“42. Dispensing by unregistered persons-

- (1) On or after such date as the State Government may by notification in the Official Gazette appoint in this behalf, no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner.

Provided that this sub-section shall not apply to the dispensing by a medical practitioner of medicine for his own patients, or with the general or special sanction of the State Government, for the patients of another medical practitioner.

Provided further that where no such date is appointed by the Government of a State, this sub-section shall take effect in that State on the expiry of a period of (eight) years from the commencement of the Pharmacy (Amendment) Act, 1976.

- (2) Whoever contravenes the provisions of sub-section (1) shall be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupees or with both.
- (3) Cognizance of an offence punishable under this section shall not be taken except upon complaint made by (order of the State Government or any officer authorised in this behalf by the State Government, or by order of the Executive Committee of the State Council)”

5. The argument of the learned counsel for the



petitioner is that Form 20 deals with sale of drugs under the Drugs and Cosmetics Rules. The restrictions contemplated under Section 42 of the Pharmacy Act will come into play only when drugs are sold by a pharmacy but where only drugs under the Drugs and Cosmetics Act are to be sold, there cannot be any condition for a Pharmacist to be engaged as there is alternatives provided in Clause (1) of the Form 20 itself.

6. We do not find any merit in the said argument.

7. Section 18 of the Drugs and Cosmetics Act, 1940 requires a licence for the purpose of manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute any drug or cosmetic. Therefore, any drug can be sold only by a person who has a licence in terms of the Drugs and Cosmetics Act, 1940 and the rules framed there-under. Rule 61 of the Drugs and Cosmetics Rules, 1945 prescribed the forms in which the licence will be issued. On the other hand, Section 42 of the Pharmacy Act put an absolute prohibition that no person other than a registered Pharmacist shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner. Even if a Medical Hall is dispensing with a medicine in the same packaging, still there is a prohibition that such medicine cannot be dispensed with by any person other than a registered Pharmacist.



8. A Full Bench of Allahabad High Court in a judgment in Ramesh Giri's case (Supra) examined the issue in respect of employment of qualified persons or Pharmacist in the retail shops of Chemist and Druggist. It was concluded as under:-

“The result of the aforesaid discussion is that a dealer holding licence in Forms 20 and 21 for retail sale of drugs is required to employ the services of qualified persons and supply such drugs under his direct supervision even if drug in a container marketed by the manufacturer is to be sold for which prescription of the registered medical practitioner is necessary.”

9. The Special Leave to Appeal (Civil) No. 21954/97 (Sharma Drug House Vs. U.O.I & Ors.) against the order dated 09.09.1997 in C.W.P. No. 16673/90 was dismissed by the Supreme Court on 12th of December, 1997 with the following observations:-

“We are surprised that it should even be urged, as the petitioner does in the present case, that it should be permitted to employ persons not duly qualified to act as Pharmacist and to handle the drugs which are sold by it. It need hardly be added that the argument does not even merit any serious consideration. While dismissing the SLP, we would like to add that in view of the perception of the petitioner it is necessary that the concerned authorities keep a strict watch over the petitioner's conduct of the business in order to ensure that the necessary statutory requirements are duly complied with by it. A copy of this order be sent by the Registrar Judicial to the Chief Secretary of the State of U.P. to ensure proper compliance not only by the petitioner but also by the like minded.

The special leave petition is dismissed with these observations.”

10. Since the identical issue has been dealt with by the



Allahabad High Court, we do not find any reason to take a contrary view other than what has been taken by the Allahabad High Court in Ramesh Giri’s case (supra).

11. Consequently, we do not find any merit in the present writ application. The same is dismissed.

(Hemant Gupta, ACJ)

Vikash Jain, J I agree.

(Vikash Jain, J)

P.K.P.

AFR/NAFR	A.F.R.
CAV DATE	02.12.2016
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