

**No person other than a Registered Pharmacist can dispense
medicine- Court judgement**

Pharmacy Council of India
File No. 2-26/2016-PCI

Extract of the common judgement/order dtd. 23.8.2017 delivered by the Hon'ble High Court of Kerala in W.P.(C).No. 37156 of 2016 and Contempt Case (C)No. 103 of 2017 regarding dispensing of medicines by persons other than registered pharmacists.

1. The Directorate of Health Services, Thiruvananthapuram vide letter No.PH2-43243/16/DHS dtd. 24.6.2016 directed the District Medical Officers (H) of various districts to restart NCD medicine distribution at sub-centre level like other national programmes and maintain the sub-centre level stock book and distribution list. This was followed by the circular dtd. 28.10.2016 stipulating how the distribution of medicines for life style diseases through sub-centres is to be effected. It is provided therein that the Junior Public Health Nurses attached to the sub-centres shall dispense medicines for Non-Communicable Disease to the patients.
2. A pharmacist registered with the Kerala State Pharmacy Council challenged the circulars dtd. 24.6.2016 and 28.10.2016 in the Hon'ble High Court of Kerala, Ernakulum in W.P.(C) No. 37156 of 2016 with the prayer to quash them and to direct the State of Kerala to implement strictly the provisions of the Pharmacy Act, 1948 and the Pharmacy Practice Regulations 2015 and not to permit any person other than the registered pharmacist to dispense medicines.
3. The Hon'ble High Court of Kerala allowed the writ petition vide common judgement/order dtd. 23.8.2017 and upheld the –
 - Provisions of section 42 of the Pharmacy Act, 1948.
 - Pharmacy Practice Regulations, 2015 of the Pharmacy Council of India.
4. The said judgement is enclosed as **Appendix-I**.
5. This is for information and compliance by all concerned.

Sd/-
(Archna Mudgal)
Registrar-cum-Secretary

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT:

THE HONOURABLE MR. JUSTICE SHAJI P. CHALY

WEDNESDAY, THE 23RD DAY OF AUGUST 2017/1ST BHADRA, 1939

WP(C).No. 37156 of 2016 (T)

PETITIONER :

SABIRA.M., W/O. MOHAMMED SALEEMK,
DARUSSALAM HOUSE, MORAYOOR POST,
MALAPPURAM DISTRICT, PIN:673642.

BY ADV. SRI.P.K.RAVISANKAR

RESPONDENTS :

1. STATE OF KERALA
REPRESENTED BY ITS ADDITIONAL CHIEF SECRETARY,
HEALTH AND FAMILY WELFARE DEPARTMENT,
SECRETARIAT, THIRUVANANTHAPURAM, PIN:695001.
2. DIRECTOR OF HEALTH SERVICES
GENERAL HOSPITAL JUNCTION,
THIRUVANANTHAPURAM, PIN:695035.
3. PHARMACY COUNCIL OF INDIA
COMBINED COUNCIL'S BUILDING, KOTLA ROAD,
AIWAN-E-GHALIB MARG, NEW DELHI-110 002.
4. KERALA STATE PHARMACY COUNCIL,
PHARMACY BHAVAN, PUBLIC HEALTH LABORATORY
CAMPUS, THIRUVANANTHAPURAM-695037.

R1 & R2 BY SP. GOVERNMENT PLEADER
SRI.N.MANOJKUMAR

R3 BY ADV. SRI.N.NAGARESH,
R4 BY ADV. SRI.P.B.SAHASRANAMAN, SC,

THIS WRIT PETITION (CIVIL) HAVING BEEN FINALLY
HEARD ON 08/08/2017, ALONG WITH COC. 103/2017,
THE COURT ON 23-08-2017 DELIVERED THE FOLLOWING:

bp

WP(C) .No. 37156 of 2016 (T)

APPENDIX

PETITIONER(S) ' EXHIBITS

- EXHIBIT P1: TRUE COPY OF THE CERTIFICATE NO.39819
DATED 11.3.2010 ISSUED BY THE 4TH
RESPONDENT.
- EXHIBIT P2: TRUE COPY OF THE DIPLOMA CERTIFICATE DATED
9.12.2009 ISSUED TO THE PETITIONER.
- EXHIBIT P3: TRUE COPY OF THE CIRCULAR NO.MSA3-
28695/12/DHS DATED 2.5.2013 ISSUED BY THE
2ND RESPONDENT.
- EXHIBIT P4: TRUE COPY OF THE CIRCULAR
NO.251991/F1/2015/H&FWD DATED 20.10.2015
ISSUED BY THE 1ST RESPONDENT.
- EXHIBIT P5: TRUE COPY OF THE ORDER DATED 18.2.2013 IN
H.R.M.P.NO.5139 OF 2011 KERALA STATE HUMAN
RIGHTS COMMISSION.
- EXHIBIT P6: TRUE COPY OF THE QUESTIONS AND ANSWERS
DATED 8.1.2014 GIVEN IN THE 13TH KERALA
LEGISLATIVE ASSEMBLY.
- EXHIBIT P7: TRUE COPY OF THE LETTER NO.PH2-
43243/16/DHS DATED 24.6.2016 ISSUED BY THE
2ND RESPONDENT.
- EXHIBIT P8: TRUE COPY OF CIRCULAR NO.PH2-43243/16/DHS
DATED 28.10.2016 ISSUED BY THE 2ND
RESPONDENT.
- EXHIBIT P9: COPY OF THE NOTE NO. M.S.A3/83501/2016/DHS
DT 22/2/2017 ISSUED BY THE R2.

RESPONDENT(S) ' EXHIBITS

- EXT.R(a): COPY OF THE RELEVANT PORTIONS OF THE
GUIDELINES ISSUED BY THE GOVERNMENT OF
INDIA

//TRUE COPY//

P.S. TO JUDGE

bp

C.R.**SHAJI P. CHALY, J.**

**W.P.(C) No.37156 of 2016 &
Cont. Case (C) No.103 of 2017**

Dated this the 23rd day of August, 2017

JUDGMENT

The writ petition and the contempt case are materially connected, and therefore, I heard them together and propose to deliver a common judgment/order. The writ petition is filed seeking to quash Exts.P7 and P8 communications issued by the 2nd respondent dated 24.06.2016 and 28.10.2016 respectively, so far as concerning the distribution of medicines through unqualified Pharmacists and for other consequential reliefs. Material facts for the disposal of the cases are as follows:

2. Petitioner is a registered pharmacist, whose name is entered in the register maintained by the 4th respondent under Sec.29 of the Pharmacy Act, 1948, evident from Ext.P1. The writ petition is filed challenging the action of the 2nd respondent, issuing orders, directing that medicines can be dispensed to patients by persons who are not qualified to do so. According to the petitioner, in terms of Sec.42 of Pharmacy Act, 1948, no other person other than a registered pharmacist shall compound, prepare, mix or dispense any

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medicine on the prescription of a medical practitioner. The 3rd and 4th respondents are constituted under Sections 3 and 19 of the Pharmacy Act, 1948 respectively.

3. The 2nd respondent issued a circular dated 02.05.2013, pointing out that many unqualified persons are performing the duties of Pharmacists in various Government Hospitals and that the same is in violation of Sec.42 of the Act and reminded all concerned that violation of the said Section is a punishable offence, evident from Ext.P3. Subsequently, Pharmacy Practice Regulations, 2015 were brought into force by the 3rd respondent. The General Council meeting of the 4th respondent held on 25.06.2015 resolved strict implementation of the said Regulations for the "safety of common man who are deprived by the irrational use of drugs". Thereupon, 1st respondent issued a circular dated 20.10.2015, directing all concerned that the instructions contained in Pharmacy Practice Regulations, 2015 shall be strictly complied with and any laxity in compliance with the regulations will be viewed seriously, evident from Ext.P4.

4. That apart, as per Ext.P5 order dated 18.02.2013, State Human Rights Commission directed that the provisions of

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the Pharmacy Act, 1948 shall be implemented in all Government and Private Hospitals, failing which, Pharmacy Inspectors shall take action including prosecution. Questions were raised in this regard in the 13th Kerala Legislative Assembly, evident from Ext.P6.

5. While so, on 24.06.2016, the 2nd respondent directed that medicines for Non-communicable Diseases shall be distributed to sub-centre clinics, evident from Ext.P7. This was followed by Ext.P8 circular dated 28.10.2016, stipulating how the distribution of medicines for life style diseases through Sub-Centres is to be effected. It is provided therein that the Junior Public Health Nurses attached to the Sub Centres shall dispense medicines for Non-communicable Diseases (NCD) to the patients. It is contended by the petitioner that the main function of Junior Public Health Nurse is field work. They are neither trained nor intended to work as curative service providers. The qualification prescribed for Junior Public Health Nurses and the Pharmacists are entirely different, and therefore, the directions contained in Exts.P7 and P8 to dispense medicines through unqualified persons cannot be sustained under law.

6. The 2nd respondent has filed a counter affidavit refuting the allegations and claims and demands raised by the petitioner. It is stated therein that the circular issued by the 2nd respondent has clearly mentioned that dispensing of the medicines from the Pharmacy shall be done only by the registered Pharmacist and the dispensed medicine shall be distributed by the Junior Public Health Nurse to needy patients who have difficulties in traveling regularly for getting medicines. That apart, it is stated that, as per circular dated 02.05.2013, only registered Pharmacist shall be dispensing medicine in Pharmacies attached to Government Hospitals and Health centres under the Health Service Department. The said circular is not related to the distribution or issue of medicine under a National Health Programme through Junior Public Health Nurse or Sub-centres. The Junior Public Health Nurse can only distribute the medicine which has been dispensed by a registered Pharmacist to the needy patients.

7. It is also stated that the circular dated 20.10.2015 has no relevance to the distribution of NCD medicines by the Junior Public Health Nurse through sub-centres, since NCD control programme is a National Programme under the

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Government of India, which is adopted at State level. The operational guidelines of prevention and screening of NCD published by the Government of India clearly states that drug distribution of NCD's shall be done through sub centres, evident from Ext.R2(a). It is also stated that the circulars issued by the Directorate as well as the directives issued by the Human Rights Commission are strictly followed and the dispensing of medicines is not done by any unqualified persons. The Junior Public Health Nurses are only distributing the medicines that are already dispensed from the District Health Centres, and therefore, the contention advanced in the writ petition cannot be sustained under law.

8. Petitioner has filed a reply to the said counter affidavit filed by the 2nd respondent, refuting the statements made in the counter affidavit, and has produced a communication issued by the 2nd respondent dated 22.02.2017, wherein, the dispensation of medicines by qualified Pharmacists is insisted upon. Therefore, according to the petitioner, the dispensation of medicine by Junior Public Health Nurse, who is unqualified was understood by the 2nd respondent and it is only to meet the requirement of the

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Pharmacy Act, 1948, Ext.P9 notification is issued by the 2nd respondent.

9. The 3rd respondent has filed a counter affidavit, contending that, the provisions of the Pharmacy Act, 1948 are to be strictly implemented, in accordance with the qualifications of the Pharmacists prescribed therein and the manner in which the duties are to be discharged by qualified Pharmacist alone. It is also submitted that the medicines are to be dispensed by a qualified Pharmacist. It is also contended that the Supreme Court as well as various High Courts have rendered judgments on that account and held that the dispensing of medicines shall only be done through qualified Pharmacists. Various judgments rendered by the Apex Court in that regard, are also recited to in the counter affidavit.

10. The 4th respondent has also filed a detailed counter affidavit narrating almost on similar lines as pointed out by the 3rd respondent, and contends that only qualified Pharmacist can dispense medicines.

11. An additional counter affidavit is filed by the 2nd respondent, reiterating the stand adopted in the counter affidavit. It is also stated therein that the circular issued by

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the 2nd respondent reserves the right of dispensing through the Pharmacist, and is only ensuring drug administration to the patient through other competent staff. Therefore, the 2nd respondent also seeks clarity in the word "dispensing" which was formulated in 1948, at a time when drugs were prepared by mixing or churning different compounds in various strengths which require special knowledge. But since drugs are now available in blister packs, the word meaning of "dispensing" shall not be misinterpreted. Moreover, the operational guidelines of all National programmes endorse drug distribution at field level, which as a State, is obliged to be executed. Various other reasons and practical difficulties are put forth by the 2nd respondent in order to dispense drug through qualified persons through sub-centres. According to the 2nd respondent, various medicines are dispensed to the sub-centres and the duty of the Junior Public Health Nurse is only to distribute them.

12. Heard learned counsel for the petitioner, learned Special Government Pleader, learned ASGI and the learned counsel appearing for the 4th respondent. Perused the documents on record and the pleadings put forth by the

respective parties.

13. The fact discussion made above would make it clear that the subject issue revolves around Sec.42 of the Pharmacy Act, 1948, dealing with dispensing by unregistered persons, which read thus:

"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 authorized in this behalf by the State Government or by order of the Executive Committee of the State Council."

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14. On a reading of the said provision, it is clear that no person other than a registered pharmacist shall compound, prepare, mix or "dispense" any medicine on the prescription of a medical practitioner. However, the said provision shall not apply to 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. Therefore, the position of law contained under Sec.42 of the Pharmacy Act is very clear. The dispensation of medicine can only be done by a qualified pharmacist and a medical practitioner for his own patients or with the general or special sanction of the State Government for the patients of another medical practitioner. Nowhere in the Pharmacy Act, 1948, the word "distribution" is employed. Why I say so, because the sole contention advanced by the 1st and 2nd respondents with respect to the point so raised by the petitioner is that, the dispensation of medicine is done at the District level by qualified/registered pharmacists in order to cater the needs of the patients who depend on the sub-centres.

15. It is true, in order to have maximum advantage of supply of medicines to the public, constitution of Sub-centres is a vital necessity. However, the medicines are dispensed by the Pharmacist from other hierarchical level of the organization, only for the purpose of storing medicines at the sub-centres. There is no doctor in the sub-centres and there is also no Pharmacist in the sub-centres, which is clear from the counter affidavit filed by the 2nd respondent. Therefore, a patient who secures prescription for the medicine from a doctor at other centres, has to approach the sub-centre to collect the medicine. Therefore, in my considered opinion, mere distribution will not suffice the situation, since there also, the prescription made by the doctor is to be identified by a qualified pharmacist in order to dispense the medicine to the patient specifically.

16. Therefore, the contention advanced by the State Government that the Junior Public Health Nurses are only distributing medicines, cannot be sustained. Various provisions of the Drugs and Cosmetics Act, 1940 were also pointed out by learned counsel for the petitioner and contends that strict adherence to the provisions of the Pharmacy Act and

the Drugs and Cosmetics Act, 1940 are mandated.

17. Learned counsel has also pointed out Schedule-K of the Drugs and Cosmetics Rules and invited my attention specifically to clause 5A thereunder, which deals with "drugs supplied by a hospital or dispensary maintained or supported by Government or local body" and the extent of its application provided thereunder which reads "the provisions of Chapter IV of the Act and the rules thereunder which require them to be covered by a sale licence, subject to the following conditions. Condition No.(1) is important, which reads thus: "the dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person".

18. Therefore, according to the learned counsel, the Junior Public Health Nurses are not having the qualification to dispense drugs. Learned counsel has also invited my attention to Regulation 2(d) of the Pharmacy Practice Regulations, 2015 which deals with "Dispensing" to mean; "the interpretation, evaluation, supply and implementation of a prescription, drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use

by, a patient". The term "Distribute" defined under Regulation 2(e) also assumes importance, which read thus: "Distribution means the delivery of a drug or device other than by administering or dispensing". "Patient counseling" is also defined under 2(f) of the Regulation, to mean; "the oral communication by the pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices". "Patient counselling" is defined under Regulation 9.3 to mean: "(a) Upon receipt of a prescription (prescription drug order) and following a review of the patient's record, a Registered Pharmacist shall personally initiate discussion of matters that will enhance or optimize drug therapy with each patient or care giver of such patient. Such discussion shall be in person, whenever practicable or by telephone and shall include appropriate elements of patient counseling". Other circumstances are also pointed out thereunder.

19. Learned Special Government Pleader appearing for the State addressed the arguments in accordance with the contentions raised in the counter affidavit as well as the additional counter affidavit and canvassed the proposition that the Junior Public Health Nurses are only distributing medicines

after dispensation from the District centre, at sub-centres, in accordance with Ext.P8 circular. However, the discussion made above with respect to the provisions of law, would make it clear that dispensing medicine can only be done by a pharmacist qualified under the Pharmacy Act, 1948. The State has no case that the Junior Public Health Nurse is also a qualified pharmacist. So much so, the qualification prescribed for Junior Public Health Nurses is entirely different from the qualification prescribed for the pharmacist under the Pharmacy Act, 1948.

20. As I have pointed out earlier, the medicines are dispensed from various other offices for the purpose of storing the same in the sub-centres. A patient diagnosed by a doctor at various levels other than the sub-centre goes to the sub-centre only for the purpose of collecting the medicine. Therefore, the patient who goes there with the prescription of the doctor, is to be dispensed with medicines as prescribed by the doctor. Merely because a Junior Public Health Nurse is able to read the prescription made by the doctor, that alone will not suffice the situation, because, as is contemplated under the Regulations, patient counseling is required.

21. So also, Schedule-K of the Drugs and Cosmetics Rules discussed above, would make an imperative condition with respect to the supply of a drug by a hospital or dispensary maintained or supported by a Government or local body, and dispensing can only be done by or under the supervision of a qualified person. The State has no case that a pharmacist is appointed in sub-centres, nor a doctor is available.

22. Therefore, taking into account the factual circumstances and reckoning the law discussed above, a Junior Public Health Nurse can only distribute the medicine from the sub-centre on the basis of the medicine dispensed by the pharmacist. However, the Government have not taken any steps to have the services of a qualified pharmacist in the sub-centres. To that extent, in my considered opinion, Exts.P7 and P8 enabling a Junior Public Health Nurse to dispense medicine from the sub-centre cannot be sustained under law. The dispensing of medicine will have to be carried out only by a qualified person, since a wrong dispensation of medicine or distribution of medicine by an unqualified person, in the absence of a qualified pharmacist, may lead to disastrous consequences. Moreover, the prescription of the doctor will

have to be identified by a qualified pharmacist and without sufficient skill with respect to the same, it cannot be heard to say that a Junior Public Health Nurse will be able to dispense medicine by reading the prescription. Here, Regulation 9.3 of the Pharmacy Practice Regulations, 2015 assumes importance, which read thus:

"9.3 Patient counselling.--(a) Upon receipt of a prescription (prescription drug order) and following a review of the patient's record, a Registered Pharmacist shall personally initiate discussion of matters that will enhance or optimize drug therapy with each patient or care given of such patient. Such discussion shall be in person, whenever practicable or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:

- (i) Name and description of the drugs
- (ii) The dosage form, dose, route of administration, and duration of drug therapy
- (iii) Intended use of the drug and expected action
- (iv) Special directions and precautions for the drugs
- (v) Common severe side effects or adverse effects or interactions and therapeutic contra indications that may be encountered, including their avoidance, and the action required if they occur;
- (vi) Techniques for self-monitoring drug therapy

- (vii) *Proper storage of the drugs*
- (viii) *Prescription refill information*
- (ix) *Action to be taken in the event of a missed dose*
- (x) *To ensure rational use of drugs.*

Note.--*The pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultations.*

(b) *The pharmacist shall maintain the records pertaining to drugs administered to the patients (drug card) that may be utilized for the evaluation of the drug therapy.*

(c) *The pharmacist is authorized (as a Health care professional) to undertake process and outcome research, health promotion and education and provide health information. Also to undertake the Pharmacoepidemiological studies.*

(d) *Pharmacies providing patient counseling shall have regard to the following:*

- (i) *Only Registered pharmacists are involved in counseling.*
- (ii) *Facilities are provided for confidential conversation and patient confidentiality is maintained.*
- (iii) *Patient information leaflets are provided.*
- (iv) *Proper documentation is made.*
- (v) *Unnecessary counseling should be avoided.*
- (vi) *Counseling for Patient's Benefit: In every consultation, the benefit to the patient is of foremost importance. All registered pharmacists engaged in the case should be frank with the patient and his attendants.*

(vii) Punctuality in counseling: Utmost punctuality should be observed by a registered pharmacist in making themselves available for counseling."

23. The said provisions are self-explanatory and are of utmost importance in the matter of dispensation of drugs to patients or their agents. A Junior Public Health Nurse distributing medicine can never be said to be an agent of a patient, at the time of receiving drugs from the distribution centre, since they are received, for stocking in the sub-centres. An agent of a patient can only be a person taking care of a patient.

24. The provisions provided under the Pharmacy Act, 1948, the Regulations, 2015, the Drugs and Cosmetics Act, 1940 and the Rules, 1945 cannot be dealt with lightly and with laxity. The provisions contained thereunder are to be strictly implemented so as to protect the interest of the patients and in order to avoid wrong administration of drugs by unqualified persons to the patients.

25. Resultantly, I am of the considered opinion that so far as the stipulations contained under Exts.P7 and P8, enabling dispensation of drugs through Junior Public Health

Nurses cannot be sustained under law. Therefore, necessary steps shall be taken by the State Government to dispense the drugs through qualified Pharmacists in accordance with law at the sub-centres. The writ petition is allowed to the above extent.

26. Now turning to the contempt case, it is true, when the writ petition was admitted to the files of this Court, an interim order was passed on 21.11.2016, directing the 2nd respondent to ensure that medicines are dispensed by qualified pharmacists, as per the provisions of the Pharmacy Act, 1948. According to the petitioner, the said interim order was not implemented by the respondents, and therefore, liable to be proceeded under the Contempt of Courts Act.

27. It is evident from the affidavit filed to the contempt case as well as the writ petition that the respondents are under a mistaken impression that once the medicine is dispensed to store at the sub-centre, further dispensing by a qualified pharmacist is not requisited under law. Moreover, the Government is under the impression that since already drugs are dispensed from other offices, by handing the same over to the patient, only a distribution takes place at the sub-centre.

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Therefore, I am of the considered opinion that, it can never be said to be a *malafide* and deliberate act on the part of the Government, in not implementing the interim order passed by this Court.

27. Therefore, in the facts and circumstances of the case, I do not propose to proceed against the respondents under the contempt of court case, since there is no deliberate or conscious contempt on the part of the respondents to violate the interim order passed by this Court. The contempt of court case is closed accordingly, holding that there is no contempt committed by the respondents as such.

Sd/-
SHAJI P. CHALY
JUDGE

//true copy//

P.S. to Judge

St/-
18.08.2017