

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT

THE HONOURABLE MR. JUSTICE P.B.SURESH KUMAR

THURSDAY, THE 25TH DAY OF FEBRUARY 2021 / 6TH PHALGUNA,
1942

WP(C).No.33715 OF 2019(L)

PETITIONERS:

- 1 ALL KERALA PHARMACISTS UNION (AKPU) ,
REGISTRATION NO.TU19354/2019, REPRESENTED BY
ITS GENERAL SECRETARY, K.P.6/2A,
MALIKAPEEDIKAYIL, MAKKAD POST, KAKKODI,
KOZHIKODE DISTRICT, PIN - 673 611.
- 2 NOBY C.P. ,
AGED 30 YEARS, S/O.GOVINDANKUTTY,
POONTHOTTATHIL HOUSE, KOODATHUMPOYIL, KAKKODI
POST, KOZHIKODE DISTRICT, PIN - 673 611.

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 - 695
001.
- 2 DIRECTOR OF HEALTH SERVICES, .
GENERAL HOSPITAL JUNCTION,
THIRUVANANTHAPURAM, PIN - 695 035.

- 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 - 695 037.
- *5 ADDITIONAL R5
ASSOCIATION OF SMALL HOSPITALS AND CLINICS -
KERALA, 'NANMA', T.C. 14/573(1) PJRRA-53A,
MEDICAL COLLEGE, THIRUVANANTHAPURAM, KERALA-
695011, REP. BY ITS SECRETARY; DR. SUSHAMA
ANIL, D/O. LATE V. KRISHNAN NAIR, AGED 56
YEARS, 'KRISHNA' HOUSE, CHELANNUR-8/2, PUNNAD
P.O., KANNAKARA, KOZIKODE DISTRICT, PIN-
673616.
ADDL.R5 IMPEADED AS PER ORDER DATED 14-01-
2021 IN IA 3/2020 IN WP(C) 33715/2019).
- R3 BY ADV. SHRI.P.VIJAYAKUMAR, ASG OF INDIA
R5 BY ADV. JACOB SEBASTIAN
R5 BY ADV. SMT.ANU JACOB
R5 BY ADV. SHRI.ANIL KUMAR K.
R5 BY ADV. SRI.K.V.WINSTON
SRI.V.MANU SPL GP

THIS WRIT PETITION (CIVIL) HAVING BEEN FINALLY HEARD
ON 25-02-2021, THE COURT ON 25-02-2021 DELIVERED THE
FOLLOWING:

C.R.**W.P.(C) No.33715 of 2019**
-----**J U D G M E N T**

The first petitioner is a trade union of pharmacists and the second petitioner is a member of the first petitioner trade union. On 24.06.2016, the second respondent, the Director of Health Services of the State Government issued Ext.P6 communication to the District Medical Officers under him to resume distribution of medicines for Non-Communicable Diseases (NCD medicines) through the Sub Centres functioning under the Primary Health Centres in the State. It is stated by the petitioners that there are no facilities in the Sub Centres for diagnosis and treatment of patients; that the Sub Centres are manned by Junior Public Health Nurses engaged in field works

concerning the various health programmes and that distribution of NCD medicines through Sub Centres would therefore contravene Section 42 of the Pharmacy Act, 1948 (the Act) which provides that no person other than a registered pharmacist shall dispense medicine on the prescription of medical practitioners. It is also stated by the petitioners that the second respondent has issued Ext.P7 circular later on 28.10.2016, authorising the Junior Public Nurses in the Sub Centres to distribute NCD medicines prescribed by doctors to the patients within their jurisdiction. Ext.P6 communication and Ext.P7 circular were challenged by one Sabira M. before this Court in W.P.(C) No.37156 of 2016 and the said writ petition was disposed of holding that the Junior Public Health Nurses shall not be permitted to dispense drugs, and directing the State Government to take necessary steps to dispense drugs through qualified pharmacists through the Sub Centres. Ext.P8

is the judgment in W.P.(C) No.37156 of 2016. It is stated by the petitioners that after Ext.P8 judgment, the second respondent has issued Ext.P9 order on 11.01.2018 prescribing the procedure to be followed for distribution of medicines to patients. In Ext.P9, it is directed that the pharmacists shall dispense NCD medicines directly to the patients for a period of three months in a labelled envelope and the same shall be entrusted to the Junior Public Health Nurses in the Sub Centres for safe keeping and periodic distribution. It was also directed in Ext.P9 order that in hospitals, in the absence of pharmacist, the Medical Officers may arrange dispensing of drugs under his/her supervision. Later, on 12.01.2018, the second respondent issued another order clarifying Ext.P9 order to the effect that arrangement for dispensation of drugs in the hospital pharmacies shall be under the direct supervision of the Medical Officers. Exts.P9 and P10 orders are under challenge in the writ

petition. The case set out by the petitioners in the writ petition is that the authorisation given to the Junior Public Health Nurses in terms of Ext.P9 order to distribute drugs to patients and the authorisation given to the Medical Officers in Exts.P9 and P10 orders to dispense drugs under their direct supervision would contravene Section 42 of the Act.

2. A counter affidavit has been filed by the second respondent. The stand taken by the second respondent in the counter affidavit is that the arrangement made in terms of Exts.P9 and P10 orders does not contravene Section 42 of the Act. The stand aforesaid was explained by the second respondent in the counter affidavit pointing out that a drug dispensed by the pharmacist can be entrusted to a third person for administration to patients and drugs can be administered by the staff nurse in the ward in the case of inpatients, and bystanders or relatives in the case of outpatients. It is also

pointed out by the second respondent that if the dispensation of drugs and its administration are not understood separately, inpatient wards in the hospitals cannot be run, as the pharmacist cannot be expected to administer drugs to each and every patients admitted in the hospital. Similarly, it was pointed out that if dispensation of the drugs and its administration are not understood distinctively, drugs which are dispensed for outpatients in the hospitals cannot be administered to them by their bystanders or relatives. It is also pointed out in the counter affidavit that administration of drugs is contemplated to be made through field staff for implementing the various National and State Level Health Programmes such as Tuberculosis Control, Leprosy Control, Anaemia Control for Antenatal women, children etc. and the said programmes cannot be implemented, if dispensation and administration are not understood distinctively. It is specifically stated that NCD

medicines are distributed through Sub Centres in terms of the operational guidelines issued by the Central Government for implementation of the Scheme of the Central Government viz, Prevention, Screening and Control of Common Non-Communicable Diseases and the purpose of such distribution is to ensure administration of drugs at the field level for patients who have inaccessibility to reach the Primary Health Centre due to their ill health, inconvenience or geographical reasons and to ensure that unavailability of the drug shall not lead to complications like heart attack, stroke, renal failure etc. It is also stated that when distribution of NCD medicines was stopped for sometime pursuant to Ext.P8 judgment, there was a huge attrition of patients, especially elderly people with limited mobility as they had to travel long distances to reach their concerned Public Health Centres for getting medicines. It is also stated by the second respondent that since monitoring of

health parameters like blood pressure and blood glucose level is mandatory at regular intervals for continuation and also for modification of drugs as per the prescribed protocol, long term issue of medicines is not practical and it is with a view to tide over this situation that Ext.P9 order has been issued. It is also stated by the second respondent that as per the practice in place, NCD medicines dispensed by the pharmacists to the patients will be entrusted to Junior Public Health Nurses at the Sub Centres and he/she will distribute the same, after monitoring the blood glucose level, blood pressure etc. It is stated that in so far as the distribution of NCD medicines is concerned, the Junior Public Health Nurses in the Sub Centres are acting only as care givers like immediate relatives for ensuring the drug compliance as per the protocol. As regards the dispensation of the drugs by Medical Officers, it is stated in the counter affidavit that dispensation of medicines under the

direct supervision of the Medical Officers does not contravene Section 42 of the Act.

3. As noted, the petitioners are aggrieved by Exts.P9 and P10 orders to the extent the same authorise the Junior Public Health Nurses in the Sub Centres of the Primary Health Centres to distribute medicines to patients under their jurisdiction and to the extent the same authorise Medical Officers to arrange dispensing of medicines under their direct supervision in hospitals, in the absence of pharmacists. The petitioners do not have a case in the pleadings that they are directly or indirectly affected by the said orders. They do not also state that the writ petition is one instituted in public interest. As the petitioners allege that the provision in Section 42 of the Act is violated flagrantly by the State Government, I do not want to dispose of the writ petition on any technical ground and instead, I wish to deal with the case on merits. The

short question that falls for consideration is as to whether Exts.P9 and P10 would contravene Section 42 of the Act.

4. Heard the learned counsel for the petitioners as also the learned Government Pleader.

5. The learned counsel for the petitioners asserted that Ext.P9 order, insofar as it authorises Junior Public Health Nurses working in Sub Centres to distribute medicines to patients, contravenes Section 42 of the Act as the same would amount to dispensing of drugs. The learned counsel relied on the definition of 'dispensing' contained in the Pharmacy Practice Regulations 2015 (the Regulations) issued under the Act to support the said contention. Similarly, it was also asserted by the learned counsel that Exts.P9 and P10 orders, insofar as it authorise the Medical Officers to arrange dispensing of drugs under their direct supervision also violate Section 42 of the Act. It was pointed out by the learned counsel that the fact that the words "except under the direct and personal supervision of a

registered pharmacist” which was originally part of subsection (1) of Section 42 have been removed subsequently would indicate the legislative intention that dispensing of medicine is not permissible even under the direct and personal supervision of the registered pharmacist. According to the learned counsel, if that were to be the legislative intention, authorising dispensation of drugs/medicines under the supervision of medical officers would certainly contravene the requirement under Section 42 of the Act.

6. Per contra, the learned Government pleader reiterated the stand in the counter affidavit that dispensing of drugs/medicines provided for under Section 42 of the Act and its administration to patients are to be understood distinctively. According to the learned Government Pleader, there is a clear distinction between administration of drug to a patient and dispensing of drug to the patient which a doctor prescribes. It

was argued that if this distinction is rightly drawn, it could be seen that the impugned orders do not offend Section 42 of the Act.

7. Sub-section (1) of Section 42 of the Act on which reliance was placed by the petitioners to substantiate their case, reads 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.”

Prior to the amendment in terms of Act 24 of 1959, sub-section (1) of 42 of the Act without its provisos stood thus :

“42(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 except under the direct and personal supervision of a registered pharmacist”.
(Underline supplied)

The word 'dispensing' is not defined in the Act. The Regulations issued under the Act, however, defines the word 'dispensing' thus:

“Dispensing” means 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 Regulations also define the word “distribute” to mean 'delivery of a drug or device other than by administering or dispensing'. It is thus clear from the aforesaid definitions itself that the Act draws a clear distinction between dispensation of drugs, its administration to patients and also distribution of drugs for the purpose of administration.

8. Reverting to the facts, the operative portion of Ext.P9 order, which is impugned in the writ petition, reads thus:

“Thus following procedures are to be followed in the distribution of medicine to patients in the institution and sub centre level.

1. For NCD drugs the Pharmacist may dispense NCD drugs for 3 months in a labelled envelope directly to the patient, which could be entrusted to the sub centre JPHN for safe keeping and periodic distribution.

2. In the Hospital Pharmacy, in the absence of Pharmacist or when the Pharmacist leaves the Pharmacy, the Medical Officer may arrange dispensing of drugs under his / her supervisions.”

Ext.P10 order is nothing but a clarification to the effect that the arrangement for dispensation of drugs by the Medical Officers shall be under their direct supervision. The operative portion of Ext.P10 order reads thus:

“In the light of the ambiguities existing in this regard, it is clarified that in the hospital pharmacy, in the absence of Pharmacist, or when the Pharmacist leaves the pharmacy, the Medical Officer may arrange dispensing of drugs under his/her direct supervision.”

No doubt, Ext.P9 order authorises Junior Public Health Nurses in the Sub Centres to keep with them NCD medicines prescribed by doctors and dispensed by the pharmacists for patients within their jurisdiction and distribute the same periodically for administration to the patients. If the said order is understood in the light of the operational guidelines of the Scheme of the Central Government namely, prevention, screening and control of common non-communicable diseases, under which NCD

medicines are distributed through Sub Centres, it is evident that the authorisation aforesaid is given, as monitoring of health parameters like blood pressure and blood glucose level is mandatory at regular intervals for continuation and for modification of drugs as per the prescribed protocol. Such an authorisation, according to me, would not amount to dispensing of medicines, but would only amount to distribution for administration.

9. That apart, the Act is a legislation of the year 1948. It is common knowledge that at that time, drugs were prepared by mixing or churning different compounds in various strengths and the said process required special knowledge. However, things have undergone a sea change. The concepts of compounding, preparing, mixing etc. of drugs have become obsolete practices of yesteryears. The drugs are now available in blister packs. The Act being an ongoing legislation, viz,

intended to apply over a period of time, according to me, the doctrine of updating construction is to be applied while interpreting its provisions. The doctrine of updating construction is premised on the principle that the provisions in the statute are to be interpreted and constructed with reference to its contemporary understanding and the constructions should be continuously updated to allow for changes, for in such legislations, the Legislature is not expected to intervene every now and then. [See Bennion on Statutory Interpretation - Fifth edition - Section 288]. I am fortified in this view by the following observation of the Apex Court in **National Textile Workers' Union v. P.R.Ramakrishnan**, (1983) 1 SCC 228 also.

“We cannot allow the dead hand of the past to stifle the growth of the living present. Law cannot stand still it must change with the changing social concepts and values. If the bark that protects the tree fails to grow and expand along with the tree, it will either choke the tree or if it is a living tree, it will shed that bark and grow a new living bark for itself.”

10. Coming to the authority given in Exts.P9 and P10 orders to the Medical Officers to dispense medicines/drugs under their direct supervision, the petitioners do not have a case that the Medical Officers are not empowered to dispense medicines to their patients. Their case, however, is only that dispensation of medicines cannot be permitted under the supervision of Medical Officers. According to them, if at all Medical Officers are dispensing drugs/medicines, they should dispense them by physically delivering the same to the patients and if dispensation is permitted under their supervision, dispensing would be done by others and such dispensation would contravene Section 42 of the Act. I do not agree. True, that portion of Section 42 of the Act authorising dispensation of medicines under the direct and personal supervision of registered pharmacists has been removed by way of

amendment to the Act, but that does not mean that the word 'dispense' in Section 42 of the Act is to be construed so narrowly to mean that either the Pharmacist or the Medical Practitioner should deliver the drugs/medicines personally to the patients or to the agents of the patients. As indicated above, Section 42 being only an ongoing provision intended for the safety of patients, having regard to the various developments took place in the field of medicines during the last several decades, it cannot be said that dispensing of medicines which now come in blister packs under the direct supervision of the Medical Officer would contravene Section 42 of the Act in any manner.

In the said view of the matter, there is no merit in the writ petition and the same is, accordingly, dismissed.

Sd/-

P.B.SURESH KUMAR, JUDGE.

YKB

APPENDIX

PETITIONER'S/S EXHIBITS:

EXHIBIT P1	TRUE COPY OF THE CERTIFICATE NO.44318 DATED 17/1/2012 ISSUED BY THE 4TH RESPONDENT TO THE 2ND PETITIONER.
EXHIBIT P2	TRUE COPY OF THE CIRCULAR NO.MSA3- 28696/12/DHS DATED 2/5/2013 ISSUED BY THE 2ND RESPONDENT.
EXHIBIT P3	TRUE COPY OF THE CIRCULAR NO.251991/F1/2015/H&FWD DATED 20/10/2015 ISSUED BY THE 1ST RESPONDENT.
EXHIBIT P4	TRUE COPY OF THE ORDER DATED 18/2/2013 IN H.R.M.P.NO.5139 OF 2011 KERALA STATE HUMAN RIGHTS COMMISSION.
EXHIBIT P4A	TRUE COPY OF THE ORDER DATED 4/3/2013 IN H.R.M.P.NO.28 OF 2014 KERALA STATE HUMAN RIGHTS COMMISSION.
EXHIBIT P5	TRUE COPY OF THE QUESTIONS AND ANSWERS DATED 8/1/2014 GIVEN IN THE 13TH KERALA LEGISLATIVE ASSEMBLY.

EXHIBIT P6	TRUE COPY OF THE LETTER NO.PH2-43243/16/DHS DATED 24/6/2016 ISSUED BY THE 2ND RESPONDENT.
EXHIBIT P7	TRUE COPY OF CIRCULAR NO.PH2-43243/16/DHS DATED 28/10/2016 ISSUED BY THE 2ND RESPONDENT.
EXHIBIT P8	TRUE COPY OF THE JUDGMENT DATED 23/8/2017 IN W.P.(C) NO.37156 OF 2016.
EXHIBIT P9	TRUE COPY OF THE ORDER NO.PH2/96525/17/DHS DATED 11/1/2018 ISSUED BY THE 2ND RESPONDENT.
EXHIBIT P10	TRUE COPY OF THE ORDER NO.PH2/96525/17/DHS DATED 12/1/2018 ISSUED BY THE 2ND RESPONDENT.
EXHIBIT P11	TRUE COPY OF THE LETTER NO.250/17 DATED 4/11/2017 ISSUED BY MEDICAL OFFICER IN CHARGE, PRIMARY HEALTH CENTRE, ELAVALLY, THRISSUR DISTRICT.
EXHIBIT P11A	TRUE COPY OF THE LETTER NO.29/18 DATED 15/2/2018 ISSUED BY MEDICAL OFFICER IN CHARGE, PRIMARY HEALTH CENTRE, AVANNUR, THRISSUR DISTRICT.
EXHIBIT P11B	TRUE COPY OF THE LETTER NO.255/17 DATED 21/11/2017 ISSUED BY MEDICAL OFFICER IN CHARGE, PRIMARY HEALTH CENTRE, PARALAM, THRISSUR DISTRICT.

EXHIBIT P11C	TRUE COPY OF THE LETTER NO.46/18 DATED 12/2/2018 ISSUED BY SUPERINTENDENT, COMMUNITY HEALTH CENTRE, KADAPPURAM, ANCHANGADY, THRISSUR DISTRICT.
EXHIBIT P11D	TRUE COPY OF THE LETTER NO.1/18 DATED 15/2/2018 ISSUED BY PUBLIC INFORMATION OFFICER, FAMILY HEALTH CENTRE, MUNDOOR, THRISSUR DISTRICT.
EXHIBIT P11E	TRUE COPY OF THE LETTER NO.8/18 DATED 5/2/2018 ISSUED BY PUBLIC INFORMATION OFFICER, PRIMARY HEALTH CENTRE, ALOOR, THRISSUR DISTRICT.
EXHIBIT P11F	TRUE COPY OF THE LETTER NO.1156/17, DATED 10/11/2017 ISSUED BY PUBLIC INFORMATION OFFICER, COMMUNITY HEALTH CENTRE, ALAPPAD, THRISSUR DISTRICT.
EXHIBIT P11G	TRUE COPY OF THE LETTER NO.191 DATED 19/12/2017 ISSUED BY MEDICAL OFFICER IN CHARGE, HEALTH CENTRE, VILVATTAM, THRISSUR DISTRICT.
EXHIBIT P11H	TRUE COPY OF THE LETTER NO.243/17 DATED 27/11/2017 ISSUED BY PUBLIC INFORMATION OFFICER, PRIMARY HEALTH CENTRE, VANIAMPARA THRISSUR DISTRICT.
EXHIBIT P11I	TRUE COPY OF THE LETTER NO.RTI589/17/9 DATED 4/1/2018 ISSUED BY PUBLIC INFORMATION OFFICER, K.KARUNAKARAN SMARAKA COMMUNITY HEALTH CENTRE, MALA, THRISSUR DISTRICT.

EXHIBIT P11J	TRUE COPY OF THE REQUEST DATED 5/6/2019 ADDRESSED TO PUBLIC INFORMATION OFFICER, DISTRICT MEDICAL OFFICE, KOZHIKODE.
EXHIBIT P11K	TRUE COPY OF THE LETTER NO.226/2019 DATED 22/6/2019 ISSUED BY PUBLIC INFORMATION OFFICER, PRIMARY HEALTH CENTRE, KAVIL, KOZHIKODE DISTRICT.
EXHIBIT P11L	TRUE COPY OF THE LETTER NO.30/17 DATED 29/1/2018 ISSUED BY PUBLIC INFORMATION OFFICER, PRIMARY HEALTH CENTRE, AYYANTHOLE, THRISSUR DISTRICT.
EXHIBIT P11M	TRUE COPY OF THE REQUEST DATED 5/6/2019 ADDRESSED TO PUBLIC INFORMATION OFFICER, DISTRICT MEDICAL OFFICE, KOZHIKODE.
EXHIBIT P11N	TRUE COPY OF THE LETTER NO.106/2019 DATED 26/6/2019 ISSUED BY MEDICAL OFFICER, PRIMARY HEALTH CENTRE, KOTTOOR, KOZHIKODE DISTRICT.
EXHIBIT P12	TRUE COPY OF THE COUNTER AFFIDAVIT FILED THE 3RD RESPONDENT IN W.P.(C) NO.37156 OF 2016.
EXHIBIT P13	TRUE COPY OF THE PETITION DATED 20/11/2019 TO THE CHIEF SECRETARY OF THE GOVERNMENT OF KERALA.
EXHIBIT P14	TRUE OF THE NOTE NO.M.S.A3/83501 /2016/DHS DATED 22.02.2017 ISSUED BY THE 2ND RESPONDENT

RESPONDENT'S/S EXHIBITS:

**EXHIBIT R2 (A) COPY OF THE GUIDELINES ISSUED BY THE
GOVERNMENT OF INDIA**

**EXHIBIT R2 (B) A COPY OF THE GOVERNMENT ORDER DATED
20.03.2020**

//TRUE COPY//

PA TO JUDGE