

**(1992) 02 AHC CK 0024**

**In the Allahabad High Court**

**Case No :** Civil Miscellaneous Writ Petition No. 9687 of 1981 and Writ Petition No"s. 13185, 12686, 11063, 11592, 11295, 12682, 10112, 13197, 14509, 14868 of 1981, 4237 of 1983, 15406 13509, 11231, 5344, 17165 of 1984, 4094, 7799, 14549, 13953 of 1985, 814, 3039, 1

J. Das Brothers

APPELLANT

Vs

Union of India (UOI) and Others

RESPONDENT

**Date of Decision :** 10-02-1992

**Acts Referred:**

Constitution of India, 1950 — Article 19(1), 19(6), 226  
Drugs and Cosmetics Rules, 1945 — Rule 3, 64, 64(1), 65, 65(1)  
Pharmacy Act, 1948 — Section 42

**Citation :** (1992) 2 AWC 1164

**Hon'ble Judges :** S.K. Dhaon, J;D.S. Sinha, J

**Bench :** Division Bench

**Advocate :** S.O.P. Agarwal, for the Appellant; Ashok Mohiley, for the Respondent

**Judgement**

S.K. Dhaon, J.—In this bunch the controversy is the same. All these petitions were heard together with a view to dispose them of finally. Accordingly, we are doing so.

2. We are taking necessary facts from writ petition No. 9687 of 1981. Initially, in this petition there were 8 Petitioners However, learned Counsel for the Petitioners scored off 7 Petitioners and, therefore, this petition is confined to M/s. J. Das and B. Das Brothers. The material facts in this petition are these. The Petitioner is a Chemist and Druggist engaged in retail business of selling manufactured drugs in the form of tablets, powders, liquids and ointments. It is not maintaining any pharmacy for compounding of drugs against the prescriptions of the medical practitioners. It deals in allopathic drugs. It is covered by the Drugs and Cosmetic Act, 1940 (hereinafter referred to as the Act). Rules have been framed under the said Act Rule 65 together with the provisions as contained in Section 42 of the Pharmacy Act, 1948 (hereinafter referred to as the Pharmacy Act) are being enforced as against the Petitioner. On the basis of the said Rules, the

Respondents insist that the Petitioner cannot carry on the business of a chemist and druggist without employing a "qualified person " On the basis of Section 42 of the Pharmacy Act, the Respondents insist that the Petitioner must employ a registered pharmacist if it wants to carry on its business. Failure to comply either with the rules or with Section 42 of the Pharmacy Act will subject it to a penal action. The prayers to the petition are these. The Respondents may be prohibited from enforcing Section 42 of the Pharmacy Act with effect from 1st September, 1981, a writ in the nature of mandamus may be issued commanding the Respondents and their subordinates to refrain from prosecuting and punishing the Petitioner for violating rule 65 (15)(c) of the Drugs and Cosmetic Rules, 1945 and Section 42 of the Pharmacy Act. The further prayer is that Rule 65 (c) of the Drugs and Cosmetic Rules as amended and Section 42 of the Pharmacy Act may be declared ultra vires as the same contravene Article 19(1)(g) of the constitution, The Respondents may be commanded to register the persons as "qualified persons" as they were doing before 31st December 1969.

3. A counter affidavit has been filed by Sri J. N. Dutta, Assistant Drugs controller (India) Directorate General of Health services, Ministry of Health, Government of India, New Delhi The material averments are these. The Act and the rules framed thereunder have been in force for over 35 years in this country. The Act regulates, the import, manufacture, distribution and sale of drugs and cosmetic with a view to ensuring that the consumer gets drugs of standard quality which are labelled properly. The Act has been amended by the Parliament on six occasions to keep in abreast with the changes that took place in the areas of pharmacy and medicines. The Commissioner, Food and Drugs Administration, Maharashtra had written to the Drugs controller (India) drawing his attention to the recommendation made by the study group constituted by the Central Council of Health and suggesting that Rule 65 (15)(c) of the Drugs and cosmetics rules be amended to provide that such persons who have not less than four years experience and who in the opinion of the licensing authority have adequate knowledge of dispensing of drugs should once again be accepted as "qualified person." The Drugs technical advisory Board considered the proposal and recommended that it would not be desirable to amend Rule 65 (15)(c) as recommended by the Central Council of Health. In April, 1979, the Central Family Welfare Council and central council of Health recommended that no amendment be made in Rule 65 (15) The council felt that it was unlikely that the country's requirements of Pharmacists would be adequately met by September, 1981 and it would be necessary to extend the date of enforcement of Section 42 of the Pharmacy Act by a period of three years to enable the States to train an adequate number of pharmacists during this period and recommended that the Pharmacy Act be amended so that Section 42 of the said Act would come into force from 1st September, 1984, instead of 1st September 1981. Accordingly, a Bill was introduced in Parliament so as to extend the date of enforcement of Section 42 from 1st September, 1981 to 1st September, 1984. Four categories of Pharmacists in service of retail pharmacy have been contemplated. They are (1)

those registered under the Pharmacy Act prior to 1962 (2) qualified persons (3) recognised as qualified under Rule 65 (15)(c) upto 31st December, 1969, and (iv) persons not recognised as qualified but have experience in dispensing. There are two categories of Pharmacists, namely "diploma holder" and "degree pharmacists". While the diploma pharmacists are generally employed in chemist shops; degree pharmacists are generally employed in factories. There is a provision in the Education Regulations that a matriculate having two years experience in dispensing could qualify for regular diploma course in Pharmacy in one year after undergoing the course. The course could also be undergone by attending day or evening classes by taking part time tuition. In this State this provision was originally followed for a period of five years and it ended on 14th December 1964. However, after the amendment of the Pharmacy Act, 1976 and after taking a stock of the situation arising out of the mandatory enforcement of Section 42 w.e.f. 1st September 1981, this provision of short term course was extended upto 31st August 1981. Thus, an additional facility was afforded to the unregistered persons to qualify themselves for registration in the State of Uttar Pradesh. There are over one lakh registered pharmacists in the country at present and fresh diploma holders in pharmacy are being turned out every year.

4. The preamble to the Act is, an Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics. Therefore, it is apparent that the regulation of distribution and sale of drugs is one of the objects of the enactment. Chapter IV of the Act deals with the manufacture, sale and distribution of drugs and cosmetics and the said chapter was enforced in this State on 1st October, 1947. Section 3(b) contains an inclusive definition of "drug". It appears to be a comprehensive definition as it, inter alia, includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body of the purpose of repelling insects like mosquitoes. It also includes all such substances intended for use as components of a drug including empty gelatin capsules. It also includes all such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals. In Section 3(f) "manufacture" too has been given an inclusive definition. According to it, in relation to any drug "manufacture" includes any process or part of a process for making, altering, ornaments finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail businesses. In Section 3(h) "patent or proprietary medicine" is defined to mean in relation to Ayurvedic, Siddha or Unani Medical System and in relation to the Allopathic system of medicine a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia or any other pharmacopoeia authorised in

this behalf by the Central Government after consultation with the Drugs Technical Advisory board. In Section 3(i) prescribed means prescribed by rules made under the Act.

5. Section 33, which falls within chapter IV, inter alia, provides that the Central Government may, after consultation with or on the recommendation of the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of the Chapter (Chapter IV) Rule 64 of the Drugs and cosmetics rules, 1945 (hereinafter referred to as the Rules) prescribes certain conditions which have to be satisfied before a licence is granted in forms 20, 20-B, 20-F, 20-G, 21 or 21-B. The proviso to rule 64 lays down that in the case of a pharmacy a licence in Form 20 or 21 shall not be granted unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with. In schedule N a list of minimum equipment for the efficient running of a pharmacy is given. The explanation to this rules says that for the purpose of the rule the term ""pharmacy" shall be held to mean and include every store or shop or other place (1) where drugs are dispensed, that is, measured or weighed or made up and supplied or (2) where prescriptions are compounded, or (3) where drugs are prepared or (4) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "pharmacy" Pharmacist, Dispensing Chemist" or Pharmaceutical chemistry or (5) which, by sign, symbol or indication within or upon it gives the impression that the operations mentioned in (1), (2) and (3) are carried out in the premises or (6) which is advertised in terms referred to in (4) above.

6. Rule 65 provides that licences in certain forms shall be subject to the conditions stated therein and to the following general conditions. We may note that it is the Petitioner's own case that it has obtained one of the licences in either of the forms mentioned in rule 65. Sub-rule (1) of rule 65 provides that any drug shall, if compounded or made on the licensee's premises be compounded or made by or under the direct and personal supervision of a qualified person Sub-rule (2) states that the supply, otherwise than by way of wholesale dealing of any drug supplied on the prescription of a Registered Medical practitioner shall be effected only by or under the personal supervision of a qualified person. It is thus clear that Sub-rule 2 emphasises that a retail dealer, who supplies any drug on the prescription of a registered Medical Practitioner, shall do so only by or under the supervision of a qualified person. Sub-rule (3) also emphasiss that the supply of any drug, other than those specified in Schedule X on a prescription of a registered medical practitioner shall be recorded etc. and in Clause (g) it is enjoined that the signature of the qualified person by or under whose supervision the medicine was made up or supplied should also be entered in the register. It is thus clear that the Rule mandates that for the supply of any drug by a retail dealer on the prescription of a registered medical practitioner the presence of a qualified person is imperative. Sub-rule (15) of rule 65 (c) states that the description "Pharmacy" "Pharmacist"

"Dispensing chemist or Pharmaceutical Chemist" shall be displayed by such licensees who employ the services of a "qualified person" and maintain a "Pharmacy" for compounding against prescriptions. The explanation is important. It says that for the purposes of Rule 65 "Qualified person" means a person who:

(a) holds a diploma or degree in pharmacy or pharmaceutical chemistry of an institute approved by the licensing authority; or

(b) is a registered pharmacist as defined in the Pharmacy Act, 1948;

Provided that in those states (including Union territories) where the first register of Pharmacist u/s 29 of the said Act has not been prepared, a person possessing qualifications to have his name entered in that register shall be deemed to be qualified person till such time as that register is prepared; or

(c) has not less than four years" practical experience of dispensing which is in the opinion of the licensing authority adequate and has been approved by that authority as a "qualified person" on or before the 31st December 1969.

7. We may at once deal with the question as to what do we understand by the expression "dispensing used in the Explanation to Clause (c) This expression has not been defined either in the Act or in the Rules. However, if we revert to rule 64, we will find that in the Explanation to Sub-rule (1) of rule 64, while defining the term Pharmacy there is a talk of drugs being dispensed. It is provided that a drug is dispensed when it is measured or weighed or made up and supplied. Applying this concept of dispensing to a retail dealer in the context of the requirement of a "qualified person" as contained in the Explanation to Sub-rule (15) of Rule 65 (c) four years practical experience in dispensing will mean the measuring or weighing or making up and supplying of drugs The position is clarified by Sub-rule (19) of Rule 65 which says that the supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only by dealers who employ the services of a "qualified person" and such supply shall be made under the direct supervision of the "qualified person" in an envelope or other suitable wrapper or container showing-name of the drug the quantity supplied and the name and address of the dealer. This shows that a retail dealer of a drug, who merely supplies or sells a drug as defined in Rule 3 (b) in the same container which the manufacturer has marketed may do so without either being a "qualified person" or employing such a person. It is a matter of common knowledge that certain drugs, as widely understood in the context of the definition, are bought by customers from a retail dealer in the same container as marketed by the manufacturer. It is also a matter of common knowledge that retail dealers, more often than not, buy drugs in a bulk which is in the container marketed by the manufacturer and thereafter sell drugs in retail in small quantity in an envelope or other suitable wrapper or container. Such transactions by a retail dealer are enjoined to be under the direct supervision of a "qualified person". Reading rules 64 and 65 together it is clear that apart from a drug contained in a container in which the manufacturer has

marketed it, no other drug can be supplied or sold by a retail dealer except by or under the supervision of a "qualified person" We have already indicated that a retail dealer is prohibited from supplying any drug on the prescription of a registered medical practitioner unless he is a "qualified person" or he is supplying the drug under the supervision of a "qualified person".

Sub-rule (19) of rule 65 does not exclude the supply in retail of any drug in an envelope or in other suitable wrapper or container etc. by a person who himself is a "qualified person". There is no conflict between Sub-rule (2) and Sub-rule (19) of rule 65. Sub-rule (2) emphasises that there can be no compounding or the manufacture of any drug or the making of a drug except under direct and personal supervision of a "qualified person". It also emphasises that in the case of a retail dealer any drug supplied on the prescription of a registered medical practitioner shall be effected only under the direct supervision of a "qualified person" whereas Sub-rule (19) does not talk of the supply of a drug on the prescription of a registered medical practitioner.

8. We may now come to the Pharmacy Act, which is an Act to regulate the profession of pharmacy. In order to have a bird's eye view as to what the Act is about, we may have a quick look at the statement of Objects and reasons of the said Act. It emphasises that only persons who have attained a minimum standard of professional education should be permitted to practice the profession of pharmacy. A general council of Pharmacy is proposed to be set up. This council will prescribe the minimum standards of education and approved courses of study and examinations for Pharmacists, and Provincial Pharmacy councils, which will be responsible for the maintenance of provincial registers of qualified pharmacists. A proposal is to empower provincial Governments to prohibit the dispensing of medicine on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a registered pharmacist,

9. In Section 2 (f) the medical practitioner has been given a very wide meaning. In Section 2 (i) "registered pharmacist" is defined to mean a person whose name is for the time being entered in the register of the State in which he is for the time being residing; or carrying on his profession or business of pharmacy. Section 3 talks of the constitution and composition of Central Council, Section 9 talks of the Executive Committee of the Central Council. Section 10 provides that the Central Council may, subject to the approval of the Central Government, make regulations, to be called the Education Regulations, prescribing the minimum standard of education required for qualification as a pharmacist. Section 12 refers to approved courses of study and examinations. Section 19 talks of the constitution and composition of State councils. Then we come to Chapter IV, which is headed as "Registration of Pharmacists." Section 29 states that the State Government shall cause to be prepared in the manner hereinafter provided a register of pharmacists for the State. Section 30 talks of the preparation of first register. In Section 31 it is provided that a person shall be entitled on payment of the prescribed fee to have his name registered and

entered in the first register if he resides, or carries on the business or profession of pharmacy and if he holds a degree or diploma in pharmacy etc. It also provides that a person who holds a degree or diploma of an Indian University other than a degree in pharmacy or pharmaceutical chemistry, and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than three years or has passed an examination recognised as adequate by the State Government for compounders or dispensers, or has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for total period of not less than five years prior to the date notified under Sub-section (2) of Section 30. Then we come to Section 42. Sub-section (1) posits that 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. The second proviso to Sub-section (1) says that where no such date is appointed by the Government of a State, Sub-section (1) shall take effect in that State on the expiry of a period of eight years from the commencement of the Pharmacy (Amendment) Act, 1976. Sub-section (2) talks of the punishment to be awarded in case of contravention of the provisions of Sub-section (2). Sub-section (3) talks of the cognizance of an offence. On a bare reading of Section 42 we find that the ban is on the compounding, preparing, mixing or dispensing of any medicine on the prescription of a medical practitioner by a person other than a registered pharmacist. We may now find as to who is a registered pharmacist. We have already referred to Section 3 (1) which defines a registered pharmacist. We have also referred to Sections 29, 30 and 31, Sub-section (d) of Section 31 may again be looked into. It may be repeated that this provision emphasises that a person who has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of medical practitioners for a certain period is qualified to have entry on first register. In this provision we may concentrate on the last part, which emphasises that a person who has been engaged in any other place where drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than five years prior to the date notified under Sub-section (2) of section, 30. Therefore, the Pharmacy Act considered a person having the age of eighteen years and who regularly dispensed on prescription of a medical practitioner for a total period of not less than five years prior to a certain cut off date as qualified for being entered on the first register. This qualification is retained in Clause (a) of Sub-section (1) of Section 32. It is thus clear that so far as the pharmacy act is concerned, it only prohibits the sale etc. of medicines and drugs on the basis of prescriptions of medical practitioners. We have seen that even the Act and the Rules framed thereunder prohibit the supply and sale by a retail dealer of drugs prescribed by a medical practitioner except [by or under the supervision of a "qualified person". We have also shown that the definition of a "qualified person"

as contained in the Explanation to Sub-rule (15) of Rule 65 includes a registered pharmacist as defined in the Pharmacy Act. Therefore, there can be no difficulty in taking the view that the Act and the Pharmacy Act should be read together.

10. We shall first deal with the argument that Section 42 of the Pharmacy Act is hit by Article 19(1)(g) of the constitution. We have referred to the Statement of Objects and Reasons giving rise to the Pharmacy Act. We have also tried to analyse the provisions of the said Act and in particular Section 42. The requirement that no other person except a registered pharmacist shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner is clearly in the public interest. Section 42, we may note, does not prohibit the sale of patent drugs etc. On the face of it, the said section does not impose a total ban upon the supply of medicines and drugs on the prescription of a medical practitioner. It only regulates that activity. This is permissible under Sub-article (6) of Article 19. Moreover, a technical or academic qualification is prescribed. No cogent argument has been advanced before us to demonstrate as to how and why Section 42 contravenes Article 19(1)(g).

11. Vires of Sub-rule (15) of Rule 65 of the Rules have also been canvassed. We have already emphasised earlier that even the Act and the rules do not impose a total ban. The dealing and sale of drugs in the same container as marketed by a manufacturer is permissible without any let or hindrance. Of course, when a dealer intends to transfer a medicine or drug from the original container to a smaller packet or container, he is required to be either a "qualified person" himself or he has to do so under the direct supervision of such a person. Likewise, if a dealer in retail is desirous to supply or sell drugs on the basis of a prescription issued by a medical practitioner, he has either to be himself a "qualified person" or he has to carry this activity under the supervision of a qualified person. This limitation upon the right to trade in drugs cannot by any stretch of imagination be called as unreasonable. The rule is a wholesome one and is in public interest. Again, no argument has been advanced before us to demonstrate as to how sub rule (15) of Rule 65 infringes Article 19(1)(g).

12. We are also not impressed with the submission that the cut off date as contained in Sub-section (2) of Section 30 has either been arbitrarily or irrationally fixed. The Act had to be enforced with full rigor. Some date of enforcement has to be fixed. A breathing time too had to be given so as to obviate, as far as possible, the inconvenience or difficulty which may be caused by the enforcement of the provisions. The cut off date, therefore, has a direct relationship or nexus with the object of the Act, namely, that no person who is not a registered pharmacist should be allowed to compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner.

13. It is settled law that there is a presumption of constitutionality of the rule. The court ought not to interpret the statutory provisions, unless compelled by their language, in such a manner as would involve its unconstitutionality, since the legislature or the rule making authority is presumed to enact a law which

does not contravene or violate the constitutional provisions. Therefore, there is a presumption in favour of constitutionality of a legislation or statutory rule unless ex facie it violates the fundamental rights guaranteed under part III of the Constitution. If the provisions of a law or the rule is construed in such a way as would make it consistent with the constitution and another interpretation would render the provision or the rule unconstitutional, the court would lean in favour of the former construction. See *M.L. Kamra Vs. The Chairman-cum-Managing Director, New India Assurance Co. Ltd. and another*, .

14. In Writ petition No. 7187 and 8599 of 1991 decided on 25th April 1986 Mr. justice Ratnavel Pandian of the Madras High Court, as he then, was, held that neither rule 65 (2) nor rule 65 (15)(c) of the Drugs and cosmetic rules nor Section 42 of the Pharmacy Act are ultra vires article 19(1)(g). We respectfully agree with the said decision.

15. An argument of despair has been advanced very vehemently on behalf of the Petitioner. It is that there is acute shortage of pharmacists in this country. Therefore, insistence upon the hiring of the services of a pharmacist or "qualified person" in substance amounts to the negation of the right conferred by Article 19(1)(g). The submission is that the practical effect of the insistence of the statute to employ either a registered pharmacist or a qualified person will be that on account of acute shortage of registered pharmacists or qualified persons the traders will perforce have to close down their business. It may or may not be true that qualified persons may not be available in abundance. On the material on record before us it is difficult, if not impossible, to come to a definite conclusion as to whether sufficient number of qualified persons are available or not, but one thing is clear and that is that the provisions of the Pharmacy Act and the drugs and Cosmetics Act and the Rules framed thereunder contain a wholesome rule in public interest and, therefore, their enforcement cannot be withheld by this Court in proceedings under Article 226 of the Constitution because some hardship is being caused to some traders. In such matters, the interest of an individual may have to be sacrificed in a larger interest. If at all, this is the precise situation, if the case of the Petitioner is accepted, we are not in a position to give any relief to the Petitioner. However, we hope and trust that if there are any practical difficulties in the way of the Petitioner in complying with the provisions of the Act, the Rules framed thereunder and the Pharmacy Act, the relevant authority shall look into the same even now and give them the necessary redress. The expression relevant authority includes the Parliament and the Rule making authority also.

16. In view of the foregoing discussion these petitions succeed in part but without any order as to costs.