

GAHC010207552021



THE GAUHATI HIGH COURT
(HIGH COURT OF ASSAM, NAGALAND, MIZORAM AND ARUNACHAL PRADESH)

Case No. : WP(C)/6559/2021

THE ASSAM PHARMACY COUNCIL AND ANR.
PHARMACY BHAWAN DIRECTOR HEALTH SERVICES CAMPUS
HENGRABARI GUWAHATI-781036 REP.BY REGISTRAR SRI JAGADISH
MISHRA

2: JAGADISH MISHRA
S/O LT. LAKHESWAR MISHRA R/O HOUSE NO. 16 ANANDI BUNGRUNG
PATH 2 NO. BIRKUCHI
NEAR OIL INDIA GATE NO. 3 BIRKUCHI NO. 2 DIST. KAMRUP (M) PIN-
781026
ASSA

VERSUS

THE STATE OF ASSAM AND 2 ORS.
REP.BY THE PRINCIPAL SECRETARY TO THE GOVT. OF ASSAM, HEALTH
AND FAMILY WELFARE DEPTT. DISPUR, GUWAHATI-781006

2:THE COMMISSIONER AND SECRETARY
TO THE GOVT. OF ASSAM
HEALTH AND FAMILY WELFARE DEPTT. DISPUR
GUWAHATI-781006

3:THE DIRECTOR OF HEALTH SERVICES
HENGRABARI
GUWAHATI-78103

Advocate for the petitioner(s): Ms. D Borgohain

Advocate for the respondent(s): Mr. DP Borah, Standing Counsel,

Health and Family Welfare Department,
Govt. of Assam.

**BEFORE
HONOURABLE MR. JUSTICE DEVASHIS BARUAH**

Date : 12-09-2024

JUDGMENT & ORDER(ORAL)

Heard Ms. D Borgohain, the learned counsel appearing on behalf of the petitioners. Mr. DP Borah, the learned counsel appears on behalf of the Health & Family Welfare Department, Govt. of Assam.

2. The petitioner No.1 is the State Pharmacy Council constituted in terms with Section 19 of the Pharmacy Act 1948, (hereinafter referred to as the 'Act of 1948'). The grievance of the petitioners herein is that the respondent State Government is not granting the sanction to the petitioner No.1 to appoint the Inspectors under Section 26A of the Act of 1948. The petitioners have assailed the inaction on the part of the State Government in not framing the Rules in terms with Section 46(2)(ff) of the Act of 1948. The petitioners have also assailed the order dated 28.07.2021, whereby the Principal Secretary to the Government of Assam, Health and Family Welfare Department has rejected the proposal of the petitioners to appoint Inspectors under Section 26A of the Pharmacy Act of 1948.

3. In order to deal with the grievance of the petitioners this Court finds it relevant to take note of the Act of 1948. The said Act of 1948 was enacted to make better provisions for the regulations of the profession and practice of pharmacy and for that purpose to constitute Pharmacy Councils.

4. Chapter II of the Act of 1948 deals with the Pharmacy Council of India. Chapter III deals with the State Pharmacy Council. Section 19 of the Act of 1948 stipulates how the State Pharmacy Council would be constituted and its composition. It is an admitted fact that the petitioner No.1 is the State Pharmacy Council. In the said Chapter III, vide an amendment i.e. the Amending Act 70 of 1976 of Section 26A was inserted which relates to Inspection. The said section is reproduced hereinunder:-

"26A. Inspection – (1) A State Council may, with the previous sanction of the State Government, appoint Inspectors having the prescribed qualifications for the purpose of Chapters III, IV and V of this Act.

(2) An Inspector may-

(a) inspect any premises where drugs are compounded or dispenses and submit a written report to the Registrar;

(b) enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist;

(c) investigate any complaint made in writing in respect of any contravention of this Act and report to the Registrar;

(d) institute prosecution under the order of the Executive Committee of the State Council;

(e) exercise such other powers as may be necessary for carrying out the purpose of Chapters III, IV and V of this Act or any rules made thereunder.

(3) Any person willfully obstructing an Inspector in the exercise of the powers conferred on him by or under this Act or any rules made thereunder shall be [liable to penalty which may extend to one lakh rupees]

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860).]"

5. From a perusal of the above quoted section, it would be seen that Inspectors are to be appointed by the State Council with the previous sanction of the State Government. The said Inspectors are required to have a prescribed qualification for the purpose of Chapter III, IV and V of the Act of 1948. The powers and functions of the Inspectors are provided in the various clauses of Sub-Section(2) of Section 26A of the Act of 1948.

6. At this stage it may be relevant to mention that Chapter IV relates to registration of pharmacist. Chapter V relates to miscellaneous, which includes, the power to impose penalty for falsely claiming to be registered pharmacist i.e. Section 41, punishment of persons, who are dispensing any medicine on prescription of a medical practitioner without being registered i.e., Section 42 etc. In the said Chapter V, Section 46 empowers the State Government, by notification in the Official Gazette to make Rules to carry out the purpose of chapter III, IV and V. The various aspect in respect to which the Rules can be made by the State Government have been enumerated in Sub-Section 2(a) to 2(l) of Section 46. For the purpose of the instant dispute, Section 46 (2)(ff) is

relevant *inasmuch* as, it is the State Government, who has to make Rules pertaining to the qualification, powers and duties of an Inspector.

7. Before further proceeding, this Court finds it relevant to take note of another two Sections in the Act of 1948:

(i) The first Section is Section 10, which relates to Educational Regulation to be made by the Pharmacy Council of India, subject to the approval of the Central Government prescribing the minimum standard of education required for qualification as a pharmacists.

(ii) The second Section is Section 18, which empowers the Central Council with the approval of the Central Government to make Regulations consistent with the Act to carry out the purposes of Chapter II.

8. This Court finds it very pertinent at this stage to take note of that Section 18 specifically deals only with Chapter II which relates to the Pharmacy Council of India and this very aspect can also be seen from Section 18(2)(f) of the Act of 1948. Section 18(2)(f) deals with qualification, the term of office and the power and duties of the Registrar, Secretary, Inspector and other Officers and servants of the Central Council, including the amount and nature of security to be furnished by the Registrar or any other Officer or Servant. In other words, the qualification, the terms of Office and the powers and duties of Inspectors of the Central Council can be prescribed by the Central Council with the approval of the Central Government by way of a Regulation. However, if this Court takes note of Section 46 (2)(ff) and reads it conjointly with Section 26A of the Act of

1948, it would be seen that the prescribed qualifications mentioned in Section 26A can only be made under Section 46 (2)(ff) of the Act of 1948 by the State Government.

9. It is pertinent to mention that the respondents State have not made the Rules in terms which Section 46 (2)(ff) of the Act of 1948. Therefore, as on date, there is no prescription on the qualifications required for appointment of an Inspector under Section 26A of the Act of 1948. There is also no Rules framed pertaining to the powers and duties of an Inspector, to be appointed, under Section 26A of the Act of 1948 and under such circumstances, the question would arise as to how any inspection is to be carried out for the purpose of Chapter III, IV and V of the Act of 1948j.

10. In the backdrop of the above, it is further pertinent to take note of that while the State Government is yet to make the Rules, in relation to the qualification, powers and duties of the Inspectors, the Central Council had framed the Regulations with the approval of the Central Government known as the 'Pharmacy Practice Regulations, 2015'. From the very preamble of the said Regulations, it would be seen that a power to make those regulations have been traced to Sections 10 and 18 of the Act of 1948 or in other words, the power in respect of making regulations in so far as prescribing the minimum standard of education required for qualification as a pharmacists as well as the various other aspects as enumerated in Section 18(2)(a) to (h) which only relates to the Central Council.

11. In the backdrop of the above, let this Court now take note of the grievances of the petitioner. In paragraph 2 of the instant judgment, this Court had referred to the grievances of the petitioners which led to the filing of the instant writ petition. Now let us see, what is the justification so forwarded by the State Government. The justifications so forwarded are:

(i) If there are two sets of Inspectors appointed i.e. under the Drugs and Cosmetics Act 1940, as well as under the Act of 1948, it would result in two sets of Inspectors: One regular Inspectors of drugs and the other Non-Government Inspectors and it would be difficult for a Pharmacy owner/Pharmacists/Drug Licenses holders to distinguish between a regular Inspector of Drugs and a Non-Government Inspector.

(ii) The second reason is that the Government will have no role in the selection process of the Non-government Inspectors, *per se*, but at the same time there will be liability on the part of the Government, if the Government grants permission for such appointments by the petitioner No.1.

(iii) The appointment of Non-Government Inspectors are not a proper substitute for ensuring good practice in Drug Administration Regulatory System. On the other hand, filling up the entry level vacant post in the cadre of Inspector of drugs timely and putting in place a proper monitoring mechanism by the Commissionerate of Foods Safety and Drug Administration seems to be more appropriate policy.

(iv). In addition to that the learned counsel appearing on behalf of the respondents tried to justify the actions of not fulfilling the mandate of the Act of 1948, on the basis of Regulation 5 of the Pharmacy Practice Regulations 2015 and submitted that on the basis of that Regulation any

Inspector can carry out the various functions as enumerated in Regulation 5(b) (i) to (vi) and, as such, there is no requirement for appointment of a Pharmacy Inspector, when Inspectors so appointed under the Drugs and Cosmetics Act, 1940 can perform the said functions.

12. I have heard the learned the counsel appearing on behalf of the parties and have given my anxious consideration to the relevant submissions. In the foregoing paragraphs of the instant judgment this Court has duly dealt with the Act of 1948 and taking into account that the State Government had taken a stand that the Inspector so appointed under the Drugs and Cosmetics Act, 1940 can also perform the functions as envisaged by a Pharmacy Inspector under the Act of 1948, this Court finds it relevant to take note of the certain provisions of the Drugs and Cosmetics Act, 1940 (for short, the 'Act of 1940').

13. Section 21 of the Act of 1940 stipulates who can appoint the Inspector as well as the powers which may be exercised by an Inspector and duties which may be performed by him. Section 22 of the Act of 1940 stipulates the powers of the Inspectors. From a perusal of Section 22, it transpires where the Inspector can inspect; what samples of any drugs or cosmetics that he can take; whom to search; enter and search any place; stop and search any vehicle, vessel or other conveyance. These powers are to be exercised by the inspector when he has reasons to believe that an offence under Chapter IV of the Act of 1940 has been committed. It is also seen from a further perusal of Section 22 of the Act of 1940, than an Inspector has the power to examine any records, register documents or other material objects found in respect to commission of

an offence under the Act of 1940 or the Rules framed thereunder. The Inspector also can require any person to produce any record, register or other document in relation to manufacture for sale or distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reasons to believe that an offence under Chapter II of the Act of 1940 has been or is being committed. In addition to that, an Inspector shall have all powers required for carrying out the purpose of Chapter II or any Rules made thereunder.

14. It is very apposite herein to mention that the power so conferred upon the Inspectors under Section 22 of the Act of 1940 has no relation to exercise the powers under the Act of 1948, and more particularly, in respect to Chapter III, IV and V of the Act of 1948.

15. It is also very pertinent to mention that in exercise of the powers conferred under Sections 6(2), 13, 33 and 33 N of the Act of 1940, the Drugs and Cosmetics Rules, 1945 (for short, the 'Rules of 1945') has been made. Rule 49 of the Rules of 1945 relates to qualifications of the Inspectors and Rule 51 relates to duties of Inspectors in premises, licensed for sale. From a perusal of the said Rules, more particularly, Rule 51 of the Rules of 1945, it does not show that the Drug Inspector, so appointed under the Act of 1940, can exercise any powers in respect to the stipulations contained in Chapter III, IV and V of the Act of 1948.

16. This Court also finds it very pertinent to take note of that inspite of the

Act of 1940, as well as the Rules of 1945 being enacted and made respectively, the Parliament thought it necessary to enact the Act of 1948 specifically to deal with the subject pertaining to the regulation of the profession and practice of pharmacy. The Act of 1948 is, therefore, a special Act. It is also further apposite to mention that inspite of the powers conferred upon the Inspectors appointed under the Act of 1940 and the Rules framed thereinunder, as discussed above, the Parliament thought it necessary to insert Section 26 A to the Act of 1948 for the purpose of carrying out inspection by Inspectors to be appointed by the State Council with the previous sanction of the State Government and to carry out the duties as envisaged in Section 26A (2) (a) to (e) of the Act of 1948. Therefore, it would be seen that both the Acts, i.e. the Act of 1940 as well as the Rules framed thereinunder and the Act of 1948 work in separate fields, and under such circumstances, it is the opinion of this Court that the Inspectors so appointed under the Act of 1940 cannot exercise the powers and duties of the Inspectors to be appointed under Section 26 A of the Act of 1948.

17. At this stage, this Court finds it relevant to take note of the submissions of Mr. DP Borah, the learned counsel for the respondents who laid emphasis on Regulation 5 of the Pharmacy Practice Regulations 2015 (for short, the Regulations of 2015) to submit that an Inspector of Drugs appointed under the Act of 1940 can also exercise the powers under the Act of 1948. The said submission is completely misconceived, inasmuch as, the Regulations of 2015 were made in exercise of the powers under Sections 10 and 18 of the Act of 1948, which, as already stated hereinabove, are in respect to prescribing the minimum standards of education as well as the power to make regulations, insofar as the Central Council is only concerned. Another reason as to why this

Court negates the said submission is for the reason Section 46(2)(ff) categorically mandates that it is the State Government, who shall make rules for prescribing the qualifications, powers and duties of the Inspector.

18. In view of the above, let this Court further consider as to whether the justification so given by the State Government in the impugned communication that there is no requirement of having Inspectors appointed under Section 26 A of the Act of 1948 is tenable or not.

19. The first justification pertains to that there would be overlapping domain amongst the two sets of Inspectors appointed under the Act of 1940 and the Act of 1948 and it shall be difficult for the pharmacy owners/pharmacist /drug license holders to distinguish between a regular Inspector of drugs and a Non-Government Inspector, and it would result in a parallel drug administration outside the purview of the Government. The said justification in the opinion of this Court is not only completely misconceived, but it is also contrary to both the Acts of 1940 and the Act of 1948, *inasmuch as* stated above, the Inspectors so appointed under the Act of 1940 would exercise powers in terms with Section 22 of the Act of 1940 and as well as Rule 51 of the Rules of 1945, which do not cover the field as is to be performed by the Inspectors to be appointed under the Act of 1948, more particularly, taking into account Sub-Section (2) of Section 26 A of the Act of 1948. The apprehension that there would be a parallel drug administration outside the purview of the Government is also totally misconceived and such apprehension amounts to tinkering with the wisdom of the legislature in enacting the Act of 1948, inspite of the Act of 1940

being in operation.

20. The second justification so provided is that the Government would have no role in the selection process of the Non-Government Inspectors, *per se*, but at the same time, there would be liability on the part of the Government, if the Government grants permission for such appointments to the petitioner No.1. The said justification in the opinion of this Court is further misconceived, taking into account that a perusal of Section 26 A categorically shows that the State Council may with the previous sanction of the State Government, appoint Inspectors, and as such, the Government would certainly have a say prior to granting appointment to the Inspectors. In addition to that, it seems to be a misconception on the part of the State Government to visualize that there will be liability on the part of the Government, if the Government grants permission for such appointment to the State Councils, *inasmuch as*, a perusal of Section 26 of the Act of 1948 as rightly submitted by Ms. D Borgohain, the learned counsel for the petitioners, that the liability to pay for the salary of the Inspectors, would be only upon the State Council.

21. The third justification, so given that the Inspectors, so appointed under the Act of 1948 did not seem to be a proper substitute for ensuring good practice in the drug Administration Regulatory System, is on the face of it, erroneous *inasmuch as* the inspectors so appointed under the Act of 1948, powers are only limited to what has been mentioned in Sub-Section(2) of Section 26 A of the Act of 1948. Such Inspectors would not have the powers as have been granted to the Inspectors so appointed under the Act of 1940.

22. Under such circumstances, this Court is of the opinion that the impugned communication dated 28.07.2021 is contrary to the Act of 1940 as well as the Act of 1948. It is also the opinion of this Court that the Inspectors appointed under the Act of 1940 cannot exercise the powers under Chapter III, IV and V of the Act of 1948, and more particularly, the powers conferred upon the Inspectors under the Act of 1948 in terms with Sub-Section (2) of Section 26A of the Act of 1948.

23. Under such circumstances, the instant writ petition stands disposed of with the following observation(s) and direction(s):

- (i) The Inspector, so appointed under the Act of 1940 cannot exercise the powers of Inspection in relation to Chapter III, IV and V of Act of 1948, and, more particularly, to the powers mentioned in Sub-Section (2) of Section 26 A of the Act of 1948. It is only the Inspector appointed under Section 26A of the Act of 1948 who can exercise such powers.
- (ii) The impugned communication dated 28.07.2021 being contrary to both the Act of 1940 as well as the Act of 1948, is set aside and quashed.
- (iii) The petitioner No.1 has the power to appoint Inspectors in terms with Section 26 A of the Act of 1948, however, with the previous sanction of the State Government. The previous sanction of the State Government cannot be rejected or withheld for reasons other than for giving effect to the provisions of Chapter

III, IV and V of the Act of 1948.

- (iv) The Inspectors so appointed under Section 26 A of the Act of 1948 are to be paid the remunerations by the State Council i.e., the petitioner No.1 herein.
- (v) For the purpose of giving effect to the Act of 1948 and, more particularly, to make inspections, it is the requirement of law that there has to be a prescription in respect to the qualifications, powers and duties of the Inspectors to be made by framing Rules by the State Government.
- (vi) The regulation of the profession and practice of Pharmacy can be made only by the Act of 1948, which is a special legislation and the non-framing of the Rules, more particularly, as regards prescribing the qualifications, powers and duties of the Inspector under the Act of 1948 by the State Government amounts to infraction of the mandates of the Act of 1948, and as such, this Court directs the State Government, and, more particularly, to the Commissioner and Secretary to the Government of Assam, Health and Family Welfare Department to take effective steps for making the Rules in terms with Section 46 A(ff) of the Act of 1948 at the earliest and preferably within 3(three) months from the date of the instant judgment.

24. In the peculiar facts of the case, this Court is not inclined to impose costs.

JUDGE

Comparing Assistant