



**IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION**

CIVIL APPEAL NOS. 1725-1731 OF 2023

THE STATE OF HARYANA

APPELLANT(S)

VERSUS

KRISHAN KUMAR & ORS.

RESPONDENT(S)

WITH

CIVIL APPEAL NOS. 1732-1738 OF 2023

CHETAN VERMA & ORS.

APPELLANT(S)

VERSUS

STATE OF HARYANA & ORS.

RESPONDENT(S)

WITH

CIVIL APPEAL NOS. _____ OF 2026

(@ Special Leave Petition (C) Nos. 16490-16491 of 2023)

KIRAN KUMAR M.

APPELLANT(S)

VERSUS

**THE KARNATAKA PUBLIC
SERVICE COMMISSION & ORS.**

RESPONDENT(S)

WITH

CIVIL APPEAL NO. OF 2026
(@ Special Leave Petition (C) No.)
[Diary No. 1909/2024]

PARVEEN KUMAR

APPELLANT(S)

VERSUS

STATE OF HARYANA & ANR.

RESPONDENT(S)

J U D G M E N T

J.K. MAHESHWARI

1. Leave granted.
2. The present batch of appeals concerns the challenge to the power of the State Government to prescribe the essential qualifications different from the qualification prescribed by the Central Government under Rule 49 of the Drug Rules, 1945¹ (in short, '**Drug Rules**') framed in exercise of the power under Sections 6(2), 12, 33 and 33N² of the Drugs and Cosmetics Act, 1940 (in short, '**D&C Act**') for appointment to the post of Drug Inspector (in short, '**DI**'), or Drug Control Officer (in short, '**DCO**').

¹ As amended by (Amendment) Rules, 2025.

² Chapter IVA – Provisions relating to [Ayurvedic, Siddha and Unani] Drugs.

3. These appeals arise from the proceedings in the State of Haryana and Karnataka respectively. Since there is a commonality of the facts and legal issues, they are being dealt with by this common judgment. For the sake of brevity, we are first dealing with the facts of the appeals from the State of Haryana, followed by those from the State of Karnataka.

Civil Appeal Nos. 1725-1731 of 2023, Civil Appeal Nos. 1732-1738 of 2023 and Diary No. 1909 of 2024

4. In Civil Appeal Nos. 1725-1731 of 2023 and Civil Appeal Nos. 1732-1738 of 2023, the State of Haryana and the participants, both have challenged the final impugned judgement dated 09.09.2022 of the Full Bench of the High Court of Punjab and Haryana at Chandigarh in the letters patent appeal and connected civil writ petitions, whereby the High Court answered the reference and quashed the advertisement, which was followed by the corrigendum, for appointment to the post of DCO in the State of Haryana. In Diary No. 1909 of 2024, the sole participant has challenged the final impugned judgement dated 30.09.2022 of the Single Judge of the High Court of Punjab and Haryana at Chandigarh in the writ petition, whereby the High Court disposed

of the same in terms of the Full Bench judgement of the High Court dated 09.09.2022.

5. The facts put in brief are that the Haryana Public Service Commission (in short, '**HPSC**') issued an advertisement on 07.09.2015, which was published on 10.09.2015, followed by the corrigendum dated 04.06.2019 for appointment to the post of DCO, prescribing qualification under the Haryana Food and Drugs Administration Department, Subordinate Offices (Group B) Service Rules, 2018 (in short, '**Rules of 2018**') framed in exercise of the power under the proviso to Article 309 of the Constitution of India. The essential qualification as specified was different from the qualification prescribed by the Central Government under the Drug Rules. Applying the Rules of 2018, the candidature of the participants was rejected for want of possessing the essential qualifications prescribed in the advertisement.

6. Being aggrieved, challenge was made before the High Court *inter-alia* contending that under Section 33 of the D&C Act, only the Central Government can make the rules for giving effect to the provisions of Chapter IV [Manufacture, Sale and Distribution of (Drugs and Cosmetics)] of D&C Act. Section 33(2)(b) of the D&C Act specifies that the Central Government may prescribe the

qualification and duties of Government Analysts and the qualifications of Inspectors by making such rules necessary for giving effect to the provisions of the said Chapter. It may, under Section 33(2)(n), prescribe the powers and duties of Inspectors and specify the drugs or classes of drugs of cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties can be exercised. In exercise of such powers, the Drug Rules were promulgated by the Centre, wherein Rule 49 prescribes the qualifications of a person who may be appointed as DI/DCO under the D&C Act. The proviso appended specifies that only those 'Inspectors' who possess experience in manufacture or testing or inspection, as the case may be, shall be authorised to inspect the manufacture of the substances as specified in Schedule C. Rules 51 and 52 of the Drug Rules prescribe the powers of Inspection.

7. The discord between the parties is that the State Government under the proviso to Article 309 of the Constitution of India, framed the Rules of 2018 which prescribed the qualification of DI/DCO by adding the experience as essential for appointment, akin to the proviso of Rule 49 of the Drug Rules, which was prescribed only to inspect the manufacture of the substances

mentioned in Schedule 'C' of the D&C Act. Therefore, the concern is whether addition of such qualification in Rules of 2018 is justified in the matter of appointment of DI/DCO by the State Government.

8. The High Court concluded that since Section 33 of the D&C Act empowers the Central Government to make Rules on the subject, as such, the field is occupied. Therefore, the State Government cannot frame rules under the proviso to Article 309 of the Constitution of India on the same subject for DI/DCO, prescribing additional qualifications, i.e., experience in inspecting Schedule C substance manufacturers under the Drug Rules. It was contended that the experience prescribed under proviso to Rule 49 of the Drug Rules cannot be made an essential qualification for appointment to the post of DI/DCO, therefore, it is illegal, arbitrary, discriminatory and also violative of Articles 14 and 16 of the Constitution of India.

9. When the matter travelled to the Division Bench of Punjab & Haryana High Court at Chandigarh, it was referred to the Larger Bench *vide* order dated 25.08.2021. For better understanding, the said order is necessary hence, reproduced as under:-

“The petitioner has filed this writ petition under Article 226 of the Constitution for quashing the essential qualification as prescribed in advertisement dated 7.9.2015 (Annexure P-1) for appointment to the post of Drug Inspector (Drug Control Officer) further for quashing part of Serial No.11 Appendix B under Rule 7 of the Notification issued by Food and Drugs Administration Department, Haryana Government dated 13.11.2018 (Annexure P-10) (Haryana Food and Drugs Administration Department, Subordinate Office (Group-B) Service Rules, 2018) inter alia as the same is contrary to Rule 49 of the Drugs and Cosmetics Rules, 1945.

The impugned notification dated 13.11.2018 (Annexure P-10) was issued by Governor in exercise of the powers conferred by the proviso to Article 309 of the Constitution of India.

In A.B. Krishna v. State of Karnataka; (1998) 3 SCC 495, Hon’ble Apex Court observed as follows:

“5. Rule-making power, so far as services under the Union or any State, are concerned, are vested in the President or the Governor, as the case may be, under Article 309 of the Constitution which provides as under: -

“309. Recruitment and conditions of service of persons serving the Union or a State – Subject to

the provisions of this Constitution, Acts of the appropriate Legislature may regulate the recruitment, and conditions of service of persons appointed, to public services and posts in connection with the affairs of the Union or of any State: Provided that it shall be competent for the President or such person as he may direct in the case of services and posts in connection with the affairs of the Union, and for the Governor of a State or such person as he may direct in the case of services and posts in connection with the affairs of the State, to make rules regulating the recruitment, and the conditions of service of persons appointed, to such services and posts until provision in that behalf is made by or under an Act of the appropriate Legislature under this article, and any rules so made shall have effect subject to the provisions of any such Act.”

6. It is primarily the Legislature, namely, the Parliament or the State Legislative Assembly, in whom power to make law regulating the recruitment and conditions of service of persons appointed to public services and posts, in connection with the affairs of the Union or the State, is vested. The legislative field indicated in this Article is the same as is indicated in Entry 71 of List I of the Seventh Schedule or Entry 41 of List II of that Schedule. The proviso, however, gives power to the President or the Governor to make Service Rules but this is only a transitional provision as the power under the Proviso can be exercised only so long as the Legislature does not make any Act whereby recruitment to public posts as also other conditions of service relating to that post are laid down.

7. The Rule-making function under the Proviso to Article 309 is a legislative function. Since Article 309 has to operate subject to other provisions of the Constitution, it is obvious that whether it is an Act made by the Parliament or the State Legislature which lays down the conditions of service or it is the Rule made by the President or the Governor under the Proviso to that Article, they have to be in conformity with the other provisions of the Constitution specially Articles 14, 16, 310 and 311.”

An intractable question has arisen in the present writ petition in view of provisions of Drugs and Cosmetics Act, 1940 and Notification dated 13.10.2018, Annexure P-10, issued by the State Government under Article 309 of the Constitution of India in a matter relating to recruitment of Drug Control Officers. Though, Section 21 of Drugs and Cosmetics Act, 1940 clearly lays down that appointment shall be made as per the qualifications prescribed, which would normally indicate the qualifications prescribed in Central statute. However, State Government invoked Article 309 of the Constitution of India and prescribed qualifications different from that prescribed by the Central Government. Though, undisputedly, the matter falls in the realm of List III, the State Government never choose to enact its legislation. Merely, for the purpose of laying down qualification, it invoked Article 309 of the Constitution of India. In such circumstances, it needs to be examined

whether invocation of such powers would be sustainable in law; whether it would be hit by doctrine of eclipse; whether notification needs to be examined in light of provisions of Article 252 and 254 of Constitution of India. There is no clear answer forthcoming in the judgments referred to by the parties, particularly, 'Priyanka and others versus UPSC and others, passed in CWP-14287 of 2013. There is one another judgment of this Court in LPA-1778-2016 Sachin Saggur v. State of Punjab and others decided on 15.9.2016.

However, the rules framed by Punjab Government regarding appointment of Drug Inspectors are in conformity with Rule 49 of Drugs & Cosmetics Rules, 1945 framed by Central Government, which is not so in State of Haryana. In State of Haryana, the experience prescribed in proviso to Rule 49 of Rules of 1945 framed by Central Government, has been made one of the essential qualifications for appointment as a Drug Inspector. There appears to be little doubt that the Drugs and Cosmetics Act, 1940 enacted by the Parliament under Central Statute is a complete legislation on the subject. Section 21 thereof reads as under:-

“21. Inspectors.—

(1) The Central Government or a State Government may by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest [in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section.

(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), and shall be officially subordinate to such authority 4[having the prescribed qualifications,] as the Government appointing him may specify in this behalf.”

Section 33 of the Drugs and Cosmetic Act, 1940 empowers the Central Government to frame Rules under the Act. In exercise of the powers conferred by Section 33 of the Act, the Central Government framed the Drugs and Cosmetics Rules, 1945. Rule 49 of the said Rules prescribes the qualification for appointment to the posts of Drug Inspectors. Rule 51 authorises certain Drug Inspectors to inspect the premises licensed for sale of drugs whereas Rule 52 authorises Drug Inspectors to inspect the manufacture of drugs or cosmetics. However, there is not even a whisper in the impugned advertisement dated 7.9.2015 as to whether Drug Inspectors (Drug Control Officers) are being appointed for the purpose of performing duties as prescribed under Rule 51 or Rule 52. Further, in the present case, the State invoked Article 309 of the Constitution prescribing essential qualifications for such appointments, which are at variance to those laid down in the Central Statute. Article 309 of the Constitution was invoked for the limited purpose of prescribing different qualifications. For all intents and purposes if the Central Act prevails, the experience as laid down in the proviso would not be essential qualification. However, if notification issued by the State under Article 309 of the Constitution is given effect to then experience become necessary and candidate not possessing the same cannot be considered eligible.

An important question therefore arises (1) whether State Government could have acted beyond the statutory provisions contained in the Central Act i.e. Sections 21 and 33 of the Act and Rules framed thereunder, prescribing qualifications and invoking Article 309 for this purpose.

While in the Rules of 1945, (2) whether the experience as contained in the proviso to Rule 49 of the 1945 Rules, whereas in the Rules framed by the State under Article 309 of the Constitution, the experience has been made as essential qualification. Therefore, another question arises (3) whether the Rules framed by the State under Article 309 of the Constitution would have overriding effect over the

rules framed under Central Statute, the primary legislation governing the recruitment of Drug Inspectors.

A larger Bench needs to be constituted to decide these questions. The application for vacation of stay be put up before the said Bench.”

10. In the said reference, the larger Bench by majority *vide* impugned order dated 09.09.2022 held that the State Government could not have acted beyond the scheme of the D&C Act and the Drug Rules prescribing experience as an essential qualification for appointment of DI/DCO since the field was occupied by the Rules of the Central government and hence, invoking power under the proviso to Article 309 of the Constitution of India on the subject is not proper. The primary legislation governing appointment of DI/DCO is the D&C Act and the Drug Rules framed thereunder. In its true sense, the State ought not to have framed separate rules to override the effect of central legislations.

11. The minority view, while concurring with the operative portion of the majority judgement *inter-alia* held that in the facts of the present case, the State while exercising powers under proviso to Article 309 of the Constitution of India did not act beyond the scope of the D&C Act. It was opined that the power under proviso to Article 309 of the Constitution of India could have been exercised even if the field was occupied because the State

Rules prescribing qualification to the post of DI/DCO are not in conflict with the Central Rules. It was noted that the experience contained in proviso to Rule 49 of Drug Rules can be made essential qualification looking at the duties of the Inspectors which also include the inspection of the manufacture of substances mentioned in Schedule C of Rule 52 of the Drug Rules. It was said, prescribing qualification *qua* experience as an essential for initial appointment of DI/DCO is not repugnant to the Drug Rules and does not override the same. Additionally, the Constitutional power under the proviso to Article 309 of the Constitution of India is to regulate the recruitment and conditions of service, including prescription of qualification which can be exercised by the State clarifying the provision of Article 254 of the Constitution of India. It was said that in the event of any conflict, the Drug Rules shall prevail over the Rules of 2018.

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12. Assailing the order dated 31.03.2023 passed by the Division Bench of the High Court of Karnataka at Bengaluru, allowing the writ petitions³ filed by the private respondents and setting aside

³ In Writ Petition No. 10575 of 2021 (S-KSAT) c/w Writ Petition No. 17163 of 2021 (S-KSAT).

the order dated 12.05.2021 passed by the Karnataka State Administrative Tribunal (in short “**KSAT**”), the present appeal has been filed.

13. The High Court was dealing with the similar controversy, in particular, the vires of condition No. 2⁴ in notification dated 23.03.2018 issued by the Karnataka Public Service Commission (in short, ‘**KPSC**’) inviting applications for the post of Drug Inspector. The dispute was set in motion when the interviews of few amongst the eligible candidates as per list dated 07.11.2019 were postponed on the pretext of document verification and later, their names were excluded *vide* the substituted select list dated 27.11.2020 without citing any reason, thereby altering the procedure. In the substituted list, the departmental candidates having experience in the manufacture and/or testing of the substances mentioned in Schedule C and/or C1 drugs included in the Drug Rules were brought in. Being aggrieved, original applications⁵ were filed before KSAT, which came to be dismissed *vide* common order dated 12.05.2021.

⁴ Must have put in a service of not less than eighteen months of experience in the manufacturing and/or testing of schedule C and/or C1 drugs included in the Drugs and Cosmetics Rules, 1945.

⁵ Original Application Nos. 5733-5786 of 2020 (Selection).

14. On assailing the same, the High Court considered the validity of the judgment of KSAT and held that the rule-making power to prescribe qualification for the post of Inspector is vested with the Parliament alone and no ground is ceded to the State Legislature, in line with the legislative backing of Section 38 of the D&C Act. It was further held that the operation ceded to the State is only to the extent of making appointment of Inspectors, but it in no way reserves any power and authority with the State to frame any rule, much less prescribe any criteria for eligibility of candidates for such posts. The Court was of the opinion that once the State is devoid of legislative competence to prescribe the qualification under the proviso to Article 309 of the Constitution of India, adding the qualification of experience by making rules, inconsistent with the provisions of the D&C Act and Drug Rules, is arbitrary. In this view, the judgment of KSAT was set-aside by the High Court declaring that the qualification of experience for appointment of Inspector is *ultra vires* to Section 33(2)(b) and 33(2)(n) of the D&C Act read with Rule 49 of the Drug Rules. The High Court further quashed all the endorsements and directed KPSC to re-do the select list.

Arguments advanced on behalf of the parties

15. Mr. Vikramjeet Banerjee, learned Additional Solicitor General representing the State of Haryana referring to Section 21 of the D&C Act argued that the State Government also has the authority to appoint such persons if it thinks fit having the qualification prescribed for the post of Inspector in such areas, as may be assigned to them, insofar as the power under Section 33 vested with the Central Government is not absolute. The entry 19 of List III under Schedule VII of the Constitution of India specifies '*Drugs and Poisons, subject to the provisions of entry 59 of List I with respect to opium.*' Therefore, under proviso to Article 309 of the Constitution of India, the State Government may prescribe the qualification of persons who can be appointed as DI/DCO. In exercise of such power, the Hon'ble Governor of the State of Haryana promulgated the Rules of 2018 which were notified on 13.11.2018, bringing the experience within the ambit of essential qualification and also the knowledge of Hindi or Sanskrit as one of the subjects considering the demography of the State. Such exercise of power cannot be said to be inconsistent with the D&C Act and Drug Rules since they merely prescribe the qualification for appointment of DI/DCO. The State, with intent to ensure

efficient discharge of duties by the Inspectors after their appointment, is well within its domain to include 'experience' as an essential qualification. It is further urged that the qualifications prescribed in proviso to Rule 49 of the Drug Rules and the qualifications prescribed in Appendix B is not repugnant, therefore, the High Court was not justified in allowing the writ petitions and setting aside the advertisement. In support, reliance has been placed on the judgment of **S. Satyapal Reddy Vs. Govt. of A.P.**⁶

16. Mr. Anand Sanjay M. Nuli, learned Senior Counsel in civil appeals concerning the State of Karnataka submits that the Karnataka State Civil Services Act, 1978 (in short '**KSCSA**') has been enacted by the State Government. Section 3 specifies '*Regulation of recruitment and the conditions of service.*', and as per clause (b), the State Government can make the rules for regulating the recruitment and the conditions of service to the persons appointed for the public service. Therefore, the State Government was well within its domain and the powers vested, in promulgating the 'Health and Family Welfare Services (Drugs Control Department Non-teaching staff) (Recruitment) Rules, 2013'

⁶ (1994) 4 SCC 391

(hereinafter referred to as '**Rules of 2013**'). The powers have been derived by the State Act to prescribe qualifications for the post of Drug Inspector and therefore, the recruitment notification issued on 23.03.2018 for filling 83 vacancies with condition no. 2 on the post of DI/DCO is completely within the competence of the State and consistent with the D&C Act and Drug Rules. He further submitted that his case stands on a different footing as compared to that of Haryana and urged that the findings of the High Court *qua* condition no. 2 in the notification dated 23.03.2018, prescribing "*18 months experience in manufacturing/testing of Schedule C and/or C1 drugs*" as *ultra vires* Section 33(2)(b) and (n) of the D&C Act and Rule 49 of the Drug Rules, is not correct. As such, the direction issued to KPSC to re-do the select list may also be set-aside.

17. Learned Counsel appearing on behalf of HPSC submits that the advertisement was issued in the year 2015 under the Haryana Drugs (Group B) Service Rules, 1989 (later repealed by the Rules of 2018) prescribing the experience as essential qualification. In such circumstances, the candidature of the participants who did not possess the requisite experience in terms of the Rules of 2018 and advertisement, was rightly rejected. It is

said, after participating in the process of selection, challenge as made belatedly after declaring them unsuccessful, cannot be maintained, hence, prayed for dismissal of the appeals on this ground alone.

18. Per contra, Mr. Shoeb Alam, learned Senior Counsel representing the participants in Civil Appeal Nos. 1725-1731 of 2023, has argued with vehemence that D&C Act was enacted in the year 1940. The statements of object and reasons to bring such Act makes it clear that for regulating the matters relating to control of drugs, though the subject was within the Provincial Legislative List, after the resolution was passed by Legislatures of all Provinces, it fell within the domain of the Federal Legislature. At the relevant point of time, Entry 19 of Part I of List III (Concurrent Legislative List) of the Government of India Act, 1935 (in short '**GOI Act**') deals '*the poisons and dangerous drugs*', while in List II (Provincial Legislative List), Entry 14 deals with '*public health and sanitation; hospitals and dispensaries; registration of births and deaths.*' Drugs and Cosmetics was part of public health and sanitation in List II, and not a part of List III. Since the Provincial Legislations relegated their powers to the Federal Legislature, thus, in exercise of such power, D&C Act was enacted in 1940.

19. Article 372⁷ of the Constitution of India, deals with the continuity of the legislations as they existed pre-independence, unless altered, repealed or amended by the competent Legislature or authority. Since no amendment was brought in the D&C Act either by State of Haryana or Karnataka, it carried forward post-independence uninterruptedly between the Provinces (States) and Federal (Centre). Once the Provinces (States) gave up their power to Federal (Centre) to enact laws on the matters relating to control of drugs, the Federal (Centre) occupied the field to frame rules on the subject. Therefore, in absence of any amendment by the States in the D&C Act altering the statutory framework prevailed pre-independence, any encroachment by way of framing rules in the said domain, is liable to be struck down. In the present case, the State Government by exercising its power under proviso to Article 309 of the Constitution of India, and/or under the State Act specifying the essential qualifications inconsistent with the qualification as prescribed in Rule 49 of the Drug Rules cannot operate in a field that is already occupied.

20. It is also his contention that Section 38 of the D&C Act specifies a procedure to make rules under the Act, requiring

⁷ Continuance in force of existing laws and their adaption.

approval of both the Houses of Parliament and modification, if any, shall be only after approval by both the Houses of Parliament. Therefore, the rules as enacted by the Central Government are within legislative competence and under the domain of central law. The said provisions shall have overriding effect over the rules framed by the Governor of the State in exercise of powers under proviso to Article 309 of the Constitution of India or under the State enactment. As such, he prayed that the well-considered judgments passed by the High Court of Punjab and Haryana and the High Court of Karnataka do not warrant interference in these appeals.

21. From the facts and arguments as advanced, it appears that appointment to the post of DI/DCO, in the States of Haryana or Karnataka is the subject of challenge in these appeals. In both States, the eligibility as prescribed under the Central Rules has been altered by making 'experience' an essential qualification for appointment, as per State Rules, which have been assailed. The challenge essentially is whether under the D&C Act, prescribing qualification for appointment of DI/DCO is the domain of the Centre or whether the States have power to prescribe qualification for the said posts. In absence, since the field is occupied by the

Centre, the State Government can prescribe experience as an essential qualification in addition to what has been prescribed in the Drug Rules. In such circumstances, the following questions arise for our consideration:-

- (i) Whether on conferment of power under the D&C Act to the Central Government to prescribe qualification for the post of Inspector, for which Rule 49 of the Drug Rules has been framed and the field is occupied; the State Government in exercise of power under the proviso to Article 309 of the Constitution of India may add 'experience' as an essential qualification in the rules, on the same subject?*
- (ii) Whether the High Courts while allowing the writ petitions and declaring the qualifications added by the respective State Governments as inconsistent to the Central Rules, have rightly upheld the challenge before them?*
- (iii) In the facts of the respective cases what relief can be allowed?*

APPRECIATION OF THE QUESTIONS IN SERIATIM

22. We have heard learned counsel for the parties at length on the conspectus of this case and on the questions posed hereinabove. In that context, they are being appreciated in succeeding paragraphs.

Question No. (i) and (ii)

23. Since the controversy involved in both these questions is interlinked and the provisions of the Act and the Rules are similar, to avoid repetition of facts both the issues are being dealt with and answered collectively.

24. On tracing the history of introducing the D&C Act, 1940, it is revealed that in 1937, a Bill was introduced in the Central Legislative Assembly to give effect to the recommendations of the Drugs Inquiry Committee to regulate the import, manufacture, distribution and sale of drugs in the British India. This Bill was referred to the Select Committee. The Select Committee expressed its opinion that a more comprehensive measure for uniform control of manufacture and distribution of drugs as well as of import was desirable. The Government of India, accordingly, asked the Provincial Legislatures to pass a resolution under Section 103 of the GOI Act, empowering the Federal Legislature to pass an Act.

Accordingly, to provide the control of import of drugs into the British India, control of manufacture, sale and distribution of drugs and containing the provisions in this regard and prescribing the manner of import, standards to be complied with drugs manufactured, sold or distributed in British India, the Central Government conferred the power to amend the first schedule while the Provincial Governments conferred the power to amend the second Schedule. As such, with an intent to maintain the uniformity in the standards and in other important matters, the Central Government considered it necessary and understood that any authority within the Provincial Governments conferred by the Bill in respect of the matters falling within the Provincial Legislative field would be *ultra vires* to the Central Legislature. As such, the Central Legislative Assembly after receiving the assent of the Governor General on 10.04.1940 enacted the Drugs Act, 1940 (now the Drugs and Control Act, 1940) and brought it into force. Section 103 of the GOI Act in respect of the above history is relevant, and is reproduced as thus:-

“103. *If it appears to the Legislatures of two or more Provinces to be desirable that any of the matters enumerated in the Provincial Legislative List should be regulated in those Provinces by Act of the Federal Legislature, and if resolutions to that effect are passed by all the Chambers of those Provincial Legislatures, it shall be*

lawful for the Federal Legislature to pass an Act for regulating that matter accordingly, but any Act so passed may, as respects any Province to which it applies, be amended or repealed by an Act of the Legislature of that Province.”

25. As per the GOI Act and from the above, it is clear that in the pre-independence era, on passing of the resolution by all the Chambers of Provincial Legislatures conferring power to the Federal Legislature to pass an Act to regulate the matters enumerated on the subject, the D&C Act has been brought into force. The said provision further makes it clear that after passing any enactment by Federal Legislature with respect to any Province to which it applies, the same may be amended or repealed by an act of the Legislature of that Province. Therefore, for amendment and repealing, power was given to the Legislature of the Province under the GOI Act.

26. Under the GOI Act, Entry 19 of List III (Concurrent Legislative List) deals with *‘poisons and dangerous drugs* while Entry 14 of List II (Provincial Legislative List) deals with *‘public health and sanitation; hospitals and dispensaries; registration of births and deaths’*. In the post-independence era, after coming into force of the Constitution of India, Entry 19 of List III (Concurrent List) deals with *‘drugs and poisons, subject to the provisions of Entry 59*

of List I with respect to opium.’ Therefore, re-formation of the topics and subjects was brought in the Seventh Schedule of the Constitution of India. The consequence thereof was that, the subject matter ‘*drugs and poisons*’ continued to be within the concurrent jurisdiction of the Central as well as State Legislations, maintaining the said subject at Entry 19 in the Concurrent List.

27. Article 372 of the Constitution of India deals with “*continuance in force of existing laws and their adaptation*”. The relevant part of the said Article is reproduced as under:-

“372. Continuance in force of existing laws and their adaptation.—

(1) *Notwithstanding the repeal by this Constitution of the enactments referred to in article 395 but subject to the other provisions of this Constitution, all the law in force in the territory of India immediately before the commencement of this Constitution shall continue in force therein until altered or repealed or amended by a competent Legislature or other competent authority.*

(2) *For the purpose of bringing the provisions of any law in force in the territory of India into accord with the provisions of this Constitution, the President may by order make such adaptations and modifications of such law, whether by way of repeal or amendment, as may be necessary or expedient, and provide that the law shall, as from such date as may be specified in the order, have effect subject to the adaptations and modifications so made, and any such adaptation or modification shall not be questioned in any court of law.*

(3) *Nothing in clause (2) shall be deemed—*

(a) *to empower the President to make any adaptation or modification of any law after*

the expiration of three years from the commencement of this Constitution; or

(b) to prevent any competent Legislature or other competent authority from repealing or amending any law adapted or modified by the President under the said clause.

From the above, it can be safely observed that except as provided under Article 395⁸ of the Constitution of India, “repeals” of the laws which were in force in the territory of India immediately on the commencement of the Constitution of India, shall continue to be in force until altered, repealed or amended by the Legislature or other competent authority. In addition, it is further observed that with an intent to bring the provisions of any law in force within the territory of India as per the Constitution of India, the President of India may, by order, make adaptation and modification of such law, except by way of amendment or repeal, as may be necessary or expedient. The President is restricted from making such adaptation and modification after expiry of three years from the commencement of the Constitution of India. Simultaneously, the competent legislature or other authority is at liberty to repeal or

⁸ Repeals – The Indian Independence Act, 1947, and the Government of India Act, 1935, together with all enactments amending or supplementing the latter Act, but not including the Abolition of Privy Council Jurisdiction Act, 1949, are hereby repealed.

(i) any Provincial Act or any Ordinance or Regulation made by the Governor of a Province under the Government of India Act, 1985; or

(ii) any rule, bye-law, regulation, order, modification or other instrument made under any such Provincial Act, Ordinance or Regulation;

which, immediately before the appointed day, was a law in force in any Province or part thereof, and includes, with respect to a merged territory, any law in force in such territory immediately before the appointed day which was made that territory or any part thereof by the Legislature or other competent authority of the corresponding Indian State or under the Extra-provincial Jurisdiction Act, 1947;

xx xx xx

(e) “existing law” means an existing Central law, existing Provincial law or existing State law.”

29. In view of the above, there cannot be any ambiguity that the D&C Act and the Drug Rules thereunder were made pre-independence. They were in existence in the territory of India (within Provincial areas of the States) on the appointed day i.e., 26.01.1950. Hence, the D&C Act is also subject to the amendment or repeal by the respective State Governments. It may be noted that in the facts of the case or during hearing, nothing has been brought on record to indicate that the said D&C Act was amended by the respective States, in so far as it relates to the power of prescribing the qualifications of Inspectors by the Central Government under Section 33(2)(b) and their powers under Section 33(2)(n). Therefore, the D&C Act is still in force as a

“central law” as it existed on the appointed day in the same terms and conditions, conferring power on the Central Government to prescribe the qualification of Inspectors.

30. Learned Additional Solicitor General, Mr. Banerjee and learned Senior Counsel, Mr. Nuli representing the appellants heavily relied on Sections 21 and 22, which are part of Chapter IV of the D&C Act, *inter-alia* contending that the power of the Central Government to make rules is not alien to the power of the State Governments to appoint such persons as DI/DCO, as it thinks fit. The power to appoint DI/DCO would include the power to prescribe qualifications as specified under Section 33 of the D&C Act. In order to appreciate the said argument, Sections 21, 22 and 33 of the D&C Act are relevant, therefore reproduced as thus:-

“21. Inspectors.— (1) *The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.*

(2) *The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.*

(3) No person who has any financial interest [in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section.

(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), and shall be officially subordinate to such authority [having the prescribed qualifications,] as the Government appointing him may specify in this behalf.]

22. Powers of Inspectors.— (1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,—

(a) inspect,—

(i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic;

(ii) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

(b) take samples of any drug or cosmetic, —

(i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

(ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;

(c) at all reasonable times, with such assistance, if any, as he considers necessary,—

(i) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or

- (ii) *enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or*
- (iii) *stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed,*

and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;]

(cc) examine any record, register, document or any other material object found 2 [with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c)], and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;]

(cca) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;]

(d) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

(2) The provisions of 4 [the Code of Criminal Procedure, 1973 (2 of 1974)] shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under [section 94] of the said Code.

(2A) Every record, register or other document seized under clause (cc) or produced under clause (cca) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.]

(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter [or refuses to produce any record, register or other document when so required under clause (cca) of sub-section (1),] he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.]

33. Power of Central Government to make rules. —

(1) 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 purposes of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may—

- (a) provide for the establishment of laboratories for testing and analysing drugs or cosmetics;*
- (b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;*
- (c) prescribe the methods of test or analysis to be employed in determining whether a drug or cosmetic is of standard quality;*

- (d) *prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;*
- (dd) *prescribe under clause (d) of section 17A the colour or colours which a drug may bear or contain for purposes of colouring;*
- (dda) *prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;*
- (e) *prescribe the forms of licences for the manufacture for sale or for distribution, for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same the qualifications of such authority and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;(ee)prescribe the records, registers or other documents to be kept and maintained under section 18B;*
- (eea) *prescribe the fees for the inspection (for the purposes of grant or renewal of licences) of premises, wherein any drug or cosmetic is being or is proposed to be manufactured;*
- (eeb) *prescribe the manner in which copies are to be certified under sub-section (2A) of section 22;*
- (f) *specify the diseases or ailments which a drug may not purport or claim to prevent, cure or mitigate and such other effects which a drug may not purport or claim to have;*
- (g) *prescribe the conditions subject to which small quantities of drugs may be manufactured for the purpose of examination, test or analysis;*

- (h) *require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified drug or class of drugs, and prohibit the sale, stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;*
- (i) *prescribe the conditions to be observed in the packing in bottles, packages, and other containers of drugs or cosmetics, including the use of packing material which comes into direct contact with the drugs and prohibit the sale, stocking or exhibition for sale, or distribution of drugs or cosmetics packed in contravention of such conditions;*
- (j) *regulate the mode of labelling packed drugs or cosmetics, and prescribe the matters which shall or shall not be included in such labels;*
- (k) *prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;*
- (l) *require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any patent or proprietary medicine containing such drug;*

*[***]*

- (n) *prescribe the powers and duties of Inspectors and the qualifications of the authority to which such Inspectors shall be subordinate and specify the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;*

- (o) *prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under section 26 and the fees payable therefor;*
- (p) *specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 31;*
- (q) *provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs or cosmetic or class of cosmetics; and*
- (r) *sum which may be specified by the Central Government under section 32B.*

31. After examining the contours of Section 21, indeed the power to appoint such persons as they think fit as DI/DCO, on possessing the prescribed qualification, for such area as may be assigned, is co-extensive with the Centre as well as the State Governments. In our view, the appointment of such persons ‘as it thinks fit’ is the discretion to be exercised either by the Centre or by the State Governments. But for the purpose of ‘having the prescribed qualification’ for the post of DI/DCO, Section 33(2)(b) of the D&C Act confers sole jurisdiction to Central Government and the power to publish the notification in the official Gazette and to give effect to the provisions of Chapter IV, which starts from Section 16 and ends at Section 33A. Therefore, the State Governments may have co-extensive powers to appoint DI/DCO

along with Central Government, but for the purpose of prescribing qualification of DI/DCO as per Sections 33(1) and 33(2)(b), as well as Section 33(2)(n), it is only the Central Government which has the power. As such, by an express contextual language of the enactment, the power to prescribe qualifications is with the Central Government, without giving any solace to the State Government. Therefore, to exercise the power for prescribing qualification of Inspectors, the field is occupied by the Central Legislature. In this regard, it can be clarified that the State Governments, by way of amendment or repeal post-Independence as specified in Article 372 of the Constitution of India, if exercise the power to amend; they have to take the said recourse, otherwise in the matter of prescribing the qualification of Inspectors, the field is occupied by the Central Legislation as discussed. Under the said power, Rule 49 of the Drug Rules prescribing '*Qualification of Inspectors*' cannot be permitted to be overridden by the Rules framed in exercise of proviso to Article 309 of the Constitution of India by the State or under the State statutes by the respective State Governments. In this sequence, Rule 49 of the Drug Rules is relevant, therefore, reproduced as thus:-

“49. *Qualifications of Inspectors.*

A person who is appointed as Inspector under the Act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law:

Provided that only those Inspectors-

(i) Who have not less than 18 months' experience in the manufacture of at least one of the substances specified in Schedule C, or

(ii) Who have not less than 18 months' experience in testing of at least one of the substances in Schedule C in a Laboratory approved for this purpose by the licensing authority, or

(iii) Who have gained experience of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspectors, shall be authorized to inspect the manufacture of the substances mentioned in Schedule C:]

[Provided further that the requirement as to the academic qualification shall not apply to persons appointed as Inspectors on or before the 18th day of October, 1993.]”

32. After going through the Drug Rules and the provisions as quoted hereinabove, it is necessary to refer the rules of the respective States whereby, in addition to the educational qualification, experience of inspection under Rule 51 and 52 of the Drug Rules was added and made part of essential qualification for the candidates to participate in selection as DI/DCO. In this context, the State of Haryana had framed the Haryana Drugs (Group B) Service Rules, 1989. In the Rules of 1989, 1 ½ years' experience was added with adequate knowledge of Hindi as an

essential qualification. The said Rules have been substituted by the Rules of 2018. The only difference in those is that a candidate must possess Hindi or Sanskrit up to matric or higher education, otherwise the experience as was part of Rules of 1989 has been maintained in the same terms. A comparison of Rule 49 of the Drug Rules and the Rules of 2018, with remarks, specifying the distinction in qualification for appointment to the post of DI/DCO will be revealed from the following comparative table reproduced as under:-

<p>Drugs and Cosmetics Rules, 1945 (“Drug Rules”) framed by the Central Government under Section 33(2)(b) of the Drugs and Cosmetics Act, 1940 (“D&C Act”)</p>	<p>Haryana Food and Drugs Administration Department, Subordinate Offices (Group B) Service Rules, 2018 (“Rules of 2018”) framed by the State of Haryana in exercise of power under proviso to Article 309 of the Constitution of India</p>	<p>Remarks</p>
<p>Rule 49. Qualification of Inspectors.– A person who is appointed an Inspector under the Act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences of</p>	<p>Sl. No. 4 in Appendix B to Rule 8 prescribing Academic qualifications and experience, if any, for an appointment by direct recruitment in the case of Drugs Control Officer–</p>	<p>As per the Drug Rules, prescription of experience as essential qualification is only for those</p>

<p>Medicines with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law.</p> <p>Provided that only those Inspectors–</p> <p>(i) who have not less than 18 months' experience in the manufacture of at least one of the substances specified in Schedule C, or</p> <p>(ii) who have not less than 18 months' experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority or</p> <p>(iii) who have gained experience of not less than three years in the inspection of firm manufacturing any of the substances specified in Schedule C during the tenure of</p>	<p>1. (a) Second Class Bachelor degree in Pharmacy OR Pharmaceutical Chemistry;</p> <p>(b) 1 ½ years experience in manufacturing of at least one of the substances specified in Schedule C appended to the Drugs and Cosmetics Rules, 1945; or</p> <p>1 ½ years experience in testing of at least one of the substances specified in the said Schedule C in a laboratory approved for the purpose by the licensing authority; or</p> <p>Three years experience in inspection of Firms manufacturing any of the substances specified in the said Schedules C; and</p> <p>2. Hindi or Sanskrit upto Matric or Higher Education</p>	<p>Drug Inspectors who shall be authorised to inspect the manufacture of the substances mentioned in Schedule C.</p> <p>However, the Rules of 2018 mandate the requirement of experience for the purpose of appointment to the post of Drug Inspector/Drug Control Officer, itself.</p>
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<p>their services as Drugs Inspectors;</p> <p>shall be authorised to inspect the manufacture of the substances mentioned in Schedule C</p>		
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33. In the State of Karnataka, the Rules of 2013 have been framed in exercise of the power under Section 3(1)(b) of KSCSA, wherein also the experience has been made an essential qualification for appointment to the post of DI/DCO. The same is also reproduced, showing comparison through a table, for better understanding, as under:-

Drugs and Cosmetics Rules, 1945 (“Drug Rules”) framed by the Central Government under Section 33(2)(b) of the Drugs and Cosmetics Act, 1940 (“D&C Act”)	Health and Family Welfare Services (Drugs Control Department Non-teaching Staff) (Recruitment) Rules, 2013 (“Rules of 2013”) framed under Section 3(2) of the Karnataka State Civil Services Act, 1978 (“KSCSA”)	Remarks
Rule 49. Qualification of Inspectors. – A person who is appointed an Inspector under the Act shall be a person who	Sl. No. 8 in Schedule to Rule 2 prescribing Minimum Qualifications for Drugs Inspector –	As per the Drug Rules, prescription of experience as essential

<p>has a degree in Pharmacy or Pharmaceutical Sciences of Medicines with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law.</p> <p>Provided that only those Inspectors–</p> <p>(i) who have not less than 18 months' experience in the manufacture of at least one of the substances specified in Schedule C, or</p> <p>(ii) who have not less than 18 months' experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority or</p> <p>(iii) who have gained experience of not less than three years</p>	<ol style="list-style-type: none"> 1. Must be holder of B. Pharm degree in Pharmacy. 2. Must have put in a service of not less than eighteen months of experience in the manufacturing and or testing of Schedule C and / or C1 drugs included in the Drugs and Cosmetics Rules, 1945. 	<p>qualification is only for those Drug Inspectors who shall be authorised to inspect the manufacture of the substances mentioned in Schedule C.</p> <p>However, the Rules of 2013 framed under KSCSA prescribe the experience as minimum qualification for the purpose of appointment as Drug Inspector/Drug Control Officer itself.</p>
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<p>in the inspection of firm manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspectors;</p> <p>shall be authorised to inspect the manufacture of the substances mentioned in Schedule C</p>		
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34. It will not be out of place to observe that the Drug Rules have been framed by the Central Government in exercise of the powers under 6(2), 12, 33 and 33N of the D&C Act, while the Rules of 2018 were framed by the State of Haryana in exercise of power under the proviso to Article 309 of the Constitution of India. In the State of Karnataka, the Rules of 2013 have been framed under the KSCSA. In the said context, the manner to frame the rules as prescribed under the D&C Act assumes significance on the issue, therefore, the said manner as specified in Section 38 is necessary to be referred. A perusal of the same makes it is clear that after making the rules, they were required to be approved by each House

of Parliament. Section 38 of the D&C Act as it exists by way of an amendment with effect from 15.09.1964 is reproduced as under:-

“38. Rules to be laid before Parliament.— Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.”

35. Similarly, the Rules of 2013 have been framed by the State of Karnataka in exercise of the power under Section 3(1)(b) of KSCSA. These powers are general in nature and are to be exercised by the State Government to specify the different categories of posts in the different branches of public services of the State, specifying the total number, nature of posts in such categories and scale of pay admissible to them. This power may also be exercised for regulating the recruitment and conditions of service of persons appointed to such public service within the State. Thus, it can very well be inferred that the power of the State Government within the said statute is general in nature for recruitment in public

employment in the state. However, the powers conferred under the D&C Act by a central legislation and in particular, for the appointment of DI/DCO, prescribing qualifications shall prevail over the power exercised under the State enactment for public employment in general within the state.

36. In the appeals arising from the State of Haryana, the Full Bench of the High Court of Punjab and Haryana at Chandigarh, while dealing with the competence of rules framed by the Central or State Government, observed that recruitment to the post of DI/DCO is primarily governed by the D&C Act and the Drugs Rules framed thereunder by the Central Government. The said experience added in the proviso to Rule 49 of the Drug Rules is in the context of the duties involving inspection of manufacture of substances specified in Schedule C under Rule 52. Though, the DI/DCO appointed on having qualification under Rule 49 also exercise the duties of inspection under Rule 51, as such it can be observed that the experience added to the proviso of Rule 49 of the Drug Rules cannot be elevated as qualification essential for the purpose of appointment, as envisaged by the Rules of 2018 framed under proviso to Article 309 of the Constitution of India. It is thus rightly concluded by the High Court that the power of the State

Government under proviso to Article 309 of Constitution of India to regulate the recruitment and conditions of service, including the prescription of qualification subject to the constitutional limitations. Such rules framed by the State government must be in consonance with the central statute or the Drug Rules framed under the D&C Act in the present case. In case of conflict, the Central Rules i.e., the Drug Rules shall prevail over the Rules of 2018.

37. In the appeals from the State of Karnataka, the High Court of Karnataka at Bengaluru emphasised that the State Government does not hold legislative competence to prescribe additional experience for the post of DI/DCO, and by doing so, has attempted to enter into the arena of competence occupied by the Central Government in terms of the central law. It was held that by Sections 12, 21, 33 and 33N of the D&C Act, the Parliament has, in entirety, reserved the rule-making power for the Central Government with the intent to ensure uniform standards for life saving drugs. The High Court, in reference to Section 38 of the D&C Act, held that the rules framed under the central law are required to be laid before both Houses of the Parliament, therefore, such rule-making power is exclusively vested with the Central

Government and the State Government is denuded of any authority to legislate in such occupied field.

38. In view of the above, we have examined the scheme of the D&C Act and the Drug Rules, whereby it is clear that power of appointment may be co-extensive, but the person selected or appointed must possess the qualifications as prescribed under the D&C Act. The Central Government for the purpose of Chapter IV of the D&C Act has prescribed the qualification of Inspectors i.e., DI/DCO by promulgating the Drug Rules. In the said context, Section 3(i) lays relevant emphasis while defining 'prescribed' to mean "*prescribed by the rules made under this Act.*" Therefore, prescription of the qualification of Inspectors under the D&C Act must be as prescribed by the rules made under the Act. Since such qualification is prescribed under Rule 49 of the Drug Rules, which have been framed under Section 6, 12, 33 and 33N of the D&C Act, such qualification shall be the qualification prescribed for appointment to the post of DI/DCO, and not otherwise.

39. On the said issue, the judgment of the Full Bench of the High Court of Judicature at Allahabad in the case of ***Kuldeep***

Singh Vs. State of U.P.,⁹ can profitably be referred wherein referring to provisions of D&C Act vis-à-vis Rule 49 of Drug Rules, it was held as under:-

“16. Now, we proceed to interpret the provisions of Rule 49 of the Drugs and Cosmetics Rules, 1945. The substantive part of Rule 49 specifies that in order to be appointed as an Inspector under the Act, a person must have (i) a degree in Pharmacy; or (ii) a degree in Pharmaceutical Sciences; or (iii) a degree in Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law. The first proviso, however, specifies that only those Inspectors who fulfill the experience referred to in clause (i) or (ii) or (iii) shall be authorized to inspect the manufacture of substances mentioned in Schedule C to the Rules. When a Court interprets a statutory provision, or a provision which is made by the delegate of the legislature while framing subordinate legislation, it must give effect to the plain, literal or grammatical meaning of the provision. Under the substantive part of Rule 49, the qualifications which are required to be held by an Inspector have been specified. These are mandatory requirements and before a person can be appointed as an Inspector, he must necessarily hold the educational qualifications which are prescribed in the substantive part. The proviso, however, specifies that “only those Inspectors” shall “be authorized to inspect the manufacture of substances mentioned in Schedule C” who possess the experience as set out in one of the three clauses thereto. In other words, the proviso carves out an exception. A person who holds the qualifications which are referred to in the substantive part of Rule 49, is eligible to be appointed as an Inspector. Once appointed as an Inspector, such a person would be empowered to exercise the powers which are conferred upon an Inspector under Section 21(2) and Section 22 together with Rules 51 and 52 of the Rules of 1945. However, the effect of the proviso is that only those Inspectors who fulfill the experience which is prescribed in one of the three clauses of the first proviso to Rule 49 can

⁹ 2014 SCC OnLine All 5119

be authorized to inspect the manufacture of substances mentioned in Schedule C. But for the provisions contained in the proviso to Rule 49, there would have been no embargo on an Inspector being authorized to inspect the manufacture of substances mentioned in Schedule C. The effect of the proviso is that even though a person is appointed as an Inspector, he can be authorized to inspect the manufacture of Schedule C substances only upon fulfilling the experience as prescribed in clauses (i) or (ii) or (iii) to the first proviso to Rule 49. Hence, the proviso engrafts an exception by entailing that before an Inspector can be authorized to inspect the manufacture of substances mentioned in Schedule C, he must fulfill the requisite experience as prescribed in the proviso. Clause (i) of the proviso stipulates an experience of 18 months in the manufacture of a Schedule C substance. Clause (ii) of the proviso stipulates 18 months' experience in the testing of a Schedule C substance in a laboratory approved by the licensing authority. Clause (iii) of the proviso stipulates experience which is gained of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their service as Drug Inspectors. Ex facie, clause (iii) of the proviso specifies experience which is gained during the tenure of service as a Drug Inspector and not before appointment. The second proviso to Rule 49 contains a stipulation that the requirement of academic qualifications shall not apply to those persons appointed as Inspectors on or before 18 October 1993. Rule 49 was substituted with effect from 19 October 1993. Hence, what the second proviso provides is that it protects the services of those Inspectors who had been appointed before the introduction of Rule 49 in its present form on 19 October 1993. Rule 51 specifies the duties of an Inspector to inspect premises licensed for the sale of drugs. Rule 52 specifies the duty of an Inspector "authorized to inspect the manufacture of drugs or cosmetics". Before an Inspector can be regarded as being authorized to inspect the manufacture of a Schedule C drug, he must possess the experience specified in the first proviso to Rule 49 of 1945 Rules. Consequently, the experience specified in the first proviso to Rule 49 is not a condition of eligibility or a qualification for appointment as an Inspector within the meaning of Rule 49. Undoubtedly and as a

matter of general principle, it is open to the appointing authority to prescribe the conditions of eligibility for the holding of a post. The conditions of eligibility may, in a given case, legitimately include the possession of an academic qualification and of experience even prior to appointment. But, once the field is governed by a rule which has been framed in exercise of a rule making power vested by statute, the statutory rules must govern. Where, as in the present case, the statutory rule does not incorporate a requirement of experience as a condition of appointment, a requirement of experience as a condition of eligibility can be introduced only by way of an amendment to the statutory rules. Neither the State in its administrative capacity nor, for that matter, the Court would have the power to rewrite subordinate legislation, in the present case Rule 49, by providing that the provisions contained in the first proviso to Rule 49 are an essential qualification or a condition of eligibility for appointment to the post of Inspector. What Rule 49 plainly postulates is that only those Inspectors who possess the experience specified in the first proviso can be authorized to inspect the manufacture of substances specified in Schedule C. This is in the nature of an exception, as explained earlier, since it permits only a certain category of Inspectors holding the required experience to inspect the manufacture of Schedule C substances. Plainly, the holding of experience is not a condition of eligibility or a condition for appointment.'

xxxx xxxx xxxx

24. *The statutory provision which we are interpreting in the present case has a different scheme altogether. The main part of Rule 49 of the Rules of 1945 provides the qualifications for appointment of an Inspector. The first proviso carves out an exception by stipulating that only certain categories of Inspectors would be authorized to inspect the manufacture of Schedule C substances. But for the proviso which places an embargo, a person who is appointed as an Inspector upon possessing the qualifications prescribed by the substantive part of Rule 49 would have been authorized to inspect the manufacture of substances mentioned in Schedule C. What the first proviso does is that it ensures that before an Inspector can be authorized to inspect the manufacture of a Schedule C*

substance, he or she must possess the experience stipulated in the first proviso to Rule 49. What needs to be noticed is that the proviso to Rule 49 of the Rules stipulates that only those Inspectors, who satisfy condition (i) or (ii) or (iii), shall be authorised to inspect the manufacture of the substances mentioned in Schedule 'C'. Schedule 'C' deals with only sixteen types of biological and special products. Schedule 'C(i)' deals with other special products. Schedule 'D' deals with certain other classes of drugs. For these reasons, we have come to the conclusion that the first proviso to Rule 49 does not provide an essential qualification for appointment as a Drug Inspector and the acquisition of the experience as set out in the first proviso would operate to authorize a Drug Inspector to inspect the manufacture of a Schedule C substance.”

40. The judgment of the High Court of Judicature at Allahabad has been relied upon by the High Court of Delhi on the same issue in ***Union Public Service Commission Vs. Nidhi Pandey***,¹⁰. The Delhi High Court in paragraphs 16 and 17 has held as under:-

“16. *With the benefit of the above Full Bench judgment, a careful reading of Rule 49 leaves no room for doubt that as far as the eligibility criteria for appointment of an Inspector is concerned, an Inspector must have (i) Degree in Pharmacy or (ii) Degree in Pharmaceutical Science or (iii) Degree in Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law. As far as the provisos are concerned, the same relate to those inspectors who are to be allowed to test substances and inspect establishments that manufacture certain drugs. The requirement of experience as stipulated in Rule 49 applies only after appointment and for the purpose of deciding whether a Drug Inspector is authorized to test specified substances and inspect the manufacturer of substances specified in Schedule 'C'. It is therefore impermissible in law to amend Recruitment Rules 2010 to*

¹⁰ 2020 SCC OnLine Del 1974

make the requirement of experience an essential qualification for the purpose of recruitment and appointment, when such experience is not an essential qualification stipulated in Rule 49 of the Drugs and Cosmetics Rules, 1945. The inclusion of requirement of experience in the advertisement, on the strength of the Recruitment Rules, 2010 is therefore equally untenable. It would appear that by amending its Recruitment Rules, the petitioner has in a sense, amended Rule 49 which is a statutory rule. This is clearly impermissible in law.

17. *In our view therefore, the Tribunal has correctly analysed the position based upon the interpretation given in the judgment of the Full Bench of the Allahabad High court and has correctly addressed the matter.”*

41. Both the judgments relate to the same post of DI/DCO, interpreting the provisions of the D&C Act and the Drugs Rules, and in our view, both these judgments and their ratio are rightly on the subject. We are in agreement with the view taken by the Full Bench of the High Court of Judicature at Allahabad and the High Court of Delhi with respect to interpretation of Sections 21 and 33 of the D&C Act, as well as Rule 49 of the Drug Rules and its proviso.

Doctrine of Occupied Field vis-à-vis Article 309 of the Constitution of India

42. The question of applicability of Article 309 of the Constitution of India in the context of promotional rules arose in **A.B. Krishna**

and Others Vs. State of Karnataka and Others,¹¹. In this case, the Mysore Fire Force (Cadre Recruitment) Rules, 1971 were framed by the State of Karnataka under Section 39 of the Fire Force Act, 1964, being a State Act. The 1971 Rules required qualifying an examination for the purpose of promotion. This Court upheld the applicability of the 1971 Rules over an amendment made by the Governor of Karnataka to the Karnataka Civil Services (General Recruitment) Rules, 1977 in exercise of powers under Article 309 of the Constitution of India. The observations made in this regard are necessary below for ready reference:-

“8. The Fire Services under the State Government were created and established under the Fire Force Act, 1964 made by the State Legislature. It was in exercise of the power conferred under Section 39 of the Act that the State Government made Service Rules regulating the conditions of the Fire Services. Since the Fire Services had been specially established under an Act of the legislature and the Government, in pursuance of the power conferred upon it under that Act, has already made Service Rules, any amendment in the Karnataka Civil Services (General Recruitment) Rules, 1977 would not affect the special provisions Validly made for the Fire Services. As a matter of fact, under the scheme of Article 309 of the Constitution, once a legislature intervenes to enact a law regulating the conditions of service, the power of the Executive, including the President or the Governor, as the case may be, is totally displaced on the principle of “doctrine of occupied field”. If, however, any matter is not touched by that enactment, it will be competent for the Executive to either issue executive

¹¹ (1998) 3 SCC 495

instructions or to make a rule under Article 309 in respect of that matter.

9. It is no doubt true that the rule-making authority under Article 309 of the Constitution and Section 39 of the Act is the same, namely, the Government (to be precise, the Governor, under Article 309 and the Government under Section 39), but the two jurisdictions are different. As has been seen above, power under Article 309 cannot be exercised by the Governor, if the legislature has already made a law and the field is occupied. In that situation, rules can be made under the law so made by the legislature and not under Article 309. It has also to be noticed that rules made in exercise of the rule-making power given under an Act constitute delegated or subordinate legislation, but the rules under Article 309 cannot be treated to fall in that category and, therefore, on the principle of "occupied field", the rules under Article 309 cannot supersede the rules made by the legislature."

43. In light of the facts of the present appeals and the judgment of this Court in **A.B Krishna** (Supra), we are of the considered opinion that the Doctrine of Occupied Field is applicable. The D&C Act being a central law confers power to the Central Government to prescribe the qualification for appointment of Inspectors, which has been exercised by framing the Drug Rules. Thus, it is the primary legislation on the subject and occupies the field. The Drug Rules, were framed by the Central Government in exercise of powers conferred by the D&C Act. The Rules of 2018 framed by the State of Haryana under the proviso to Article 309 of the Constitution of India cannot override the Drug Rules in so far as it relates to prescription of qualification for appointment of

Inspector. Similar is the case in the State of Karnataka where the Rules of 2013 were framed in exercise of powers under Section 3(1)(b) of the KSCSA.

44. It is therefore apposite to underscore the material distinction in the manner of framing of the two sets of Rules. While the Rules of 2013 trace their authority to a State enactment, the Drug Rules emanate from a central legislation enacted under the Concurrent List, wherein the central law, along with the Rules framed thereunder, constitutes the primary and dominant regulatory framework. Consequently, the Rules of 2013 cannot be construed so as to invalidate or prevail over the central Drug Rules.

45. Additionally, Section 33(2)(b) read with Section 33(2)(n) of the D&C Act confer exclusive jurisdiction upon the Central Government to frame rules for the purpose of appointment of Inspector. '***Expressio unius est exclusio alterius***' means the "*express mention of one thing excludes others.*" This internal aid to statutory interpretation further reinforces the legislative intent that the power to prescribe qualifications and conditions for appointment of Inspectors vests exclusively with the Central Government under the D&C Act. Once the Centre has consciously and expressly occupied the field by placing the Drug Rules framed

under the D&C Act before both Houses of the Parliament as provided under Section 38, any inconsistent exercise of power by the State, even under the proviso to Article 309 of the Constitution of India, stands impliedly excluded.

46. Reverting to the issue as raised regarding inconsistency between the laws made by the Parliament and the laws made by legislature of the State is also a point which requires consideration. As discussed, the power for appointment to the post of DI/DCO is co-extensive with the Central and State Governments, and they may assign the duties as they think fit. As analysed above, under the D&C Act, the power to prescribe the qualification of Inspectors is the domain of the Central Government. In the previous paragraphs, it is also said that the provisions of the D&C Act regarding power of the Central Government to prescribe the qualification has not been amended by the respective States. Since the subject matter is under Entry No. 19 by Concurrent List of List III, therefore, on the subject occupied by the Central Legislation, the power of State legislation does not flow to the State on the subject so occupied.

47. Learned Additional Solicitor General, Mr. Vikramjeet Banerjee appearing on behalf of the State of Haryana has heavily

placed reliance on the judgment of **S. Satyapal Reddy** (Supra) wherein the qualification for appointment on the post of Assistant Motor Vehicles Inspector in the State of Andhra Pradesh as per State rules was an issue. In the facts of the said case, the Central Government framed the rules in exercise of power under Section 213(4) of the Motor Vehicles Act, 1988 *vide* S.O.443(E) dated 12.06.1989 prescribed a diploma in Mechanical Engineering as the ‘minimum qualification’ for appointment to the said post. The Government of Andhra Pradesh in exercise of powers under proviso to Article 309 of the Constitution of India, framed the Andhra Pradesh Transport Subordinate Service Rules, 1984 and enhanced the qualification of diploma into degree as qualification for appointment. In the said context, this Court held as under: -

*“5. ...It is seen that marginal note in Section 213 for “appointment of Motor Vehicles Officers” indicates the subject-matter of the section. Sub-section (1) says that the State Government may, for the purpose of carrying into effect the provisions of this Act, establish Motor Vehicles Department and “appoint as officers thereof such persons as it thinks fit”. The power of appointment includes the power to select a fit and competent person who it thinks fit to hold the post and would discharge efficiently the functions assigned under the Act. **It includes the power to prescribe qualifications to select suitable officers.** The Parliament preserved that power to the State Government under Section 213(1) itself by allowing it to appoint the officers whom it finds fit to carry into effect the provisions of the Act. Sub-section (4) gives power to the Central Government, having regard to the object of the Act,*

*by a notification in the Official Gazette “to prescribe minimum qualification” which the officers or class of officers thereof shall possess for being appointed as such officer or to the cadre belonging to the State Government. Under Entry 41 of List II (State List) of VIIIth Schedule to the Constitution, the public service includes the services of the officers to be appointed under sub-section (1) of Section 213 of the Act. No doubt, as contended by the learned counsel for the appellants that the Act receives paramountcy, since under Entry 35, the subject under the Act covers the concurrent field. **Sub-section (4) of Section 213 also preserves the power to prescribe qualifications higher than that “minimum qualification” prescribed by the Central Government to appoint the “said officers or any class thereof shall possess for being appointed as such.”***

48. In light of the said observations, if we examine the scheme of the Motor Vehicles Act, 1988, Section 213 deals with the appointment of Assistant Motor Vehicle Inspectors. Sub-section (iv) therein confers power on the Central Government to prescribe the ‘minimum qualification’ which the said officers or any class thereof shall possess for being appointed as such. However, prescribing the ‘minimum qualification’ i.e., holding a diploma in Mechanical Engineering was ‘minimum’. Section 213(iii) of the Motor Vehicles Act, 1988 also confers powers on the State Government to make rules for regulating the discharge of functions by officers of the motor vehicle department and in particular, and without prejudice to the generality of forgoing power, prescribe the uniform to be worn by them, the authorities to which they shall be

sub-ordinate, the duties to be performed by them, the powers (including the powers exercisable by police officers under this Act) to be exercised by them and the conditions governing the exercise of such power. Therefore, to sustain the discharge of the duties of the powers were given to the State Government. In the said case, the State Government by its rules under the proviso to Article 309 of the Constitution of India prescribed the educational qualification as a degree in Mechanical Engineering for the post of Assistant Motor Vehicle Inspector. However, the said qualification was above that prescribed by the Central Government i.e., a diploma in Mechanical Engineering which was the minimum qualification. This Court while dealing with the issue has observed as under: -

*“7. It is thus settled law that Parliament has exclusive power to make law with respect to any of the matters enumerated in List I or concurrent power with the State Legislature in List III of the VIIth Schedule to the Constitution which shall prevail over the State law made by the State Legislature exercising the power on any of the entries in List III. If the said law is inconsistent with or incompatible to occupy the same field, to that extent the State law stands superseded or becomes void. **It is settled law that when Parliament and the Legislature derive that power under Article 246(2) and the entry in the Concurrent List, whether prior or later to the law made by the State Legislature, Article 246(2) gives power, to legislate upon any subject enumerated in the Concurrent List, the law made by Parliament gets paramountcy over the law made by the State***

Legislature unless the State law is reserved for consideration of the President and receives his assent. Whether there is an apparent repugnance or conflict between Central and State laws occupying the same field and cannot operate harmoniously in each case the court has to examine whether the provisions occupy the same field with respect to one of the matters enumerated in the Concurrent List and whether there exists repugnancy between the two laws. Article 254 lays emphasis on the words “with respect to that matter”. Repugnancy arises when both the laws are fully inconsistent or are absolutely irreconcilable and when it is impossible to obey one without disobeying the other. The repugnancy would arise when conflicting results are produced when both the statutes covering the same field are applied to a given set of facts. But the court has to make every attempt to reconcile the provisions of the apparently conflicting laws and the court would endeavour to give harmonious construction. The purpose to determine inconsistency is to ascertain the intention of Parliament which would be gathered from a consideration of the entire field occupied by the law. The proper test would be whether effect can be given to the provisions of both the laws or whether both the laws can stand together. Section 213 itself made the distinction of the powers exercisable by the State Government and the Central Government in working the provisions of the Act. It is the State Government that operates the provisions of the Act through its officers. Therefore, sub-section (1) of Section 213 gives power to the State Government to create Transport Department and to appoint officers, as it thinks fit. Sub-section (4) thereof also preserves the power. **By necessary implication, it also preserves the power to prescribe higher qualification for appointment of officers of the State Government to man the Motor Vehicles Department. What was done by the Central Government was only the prescription of minimum qualifications, leaving the field open to the State Government concerned to prescribe if it finds necessary, higher qualifications.** The Governor has been given power under proviso to Article 309 of the Constitution, subject to any law made by the State Legislature, to make rules regulating the recruitment which includes prescription of qualifications for appointment to an

office or post under the State. Since the Transport Department under the Act is constituted by the State Government and the officers appointed to those posts belong to the State service, while appointing its own officers, the State Government as a necessary adjunct is entitled to prescribe qualifications for recruitment or conditions of service. But while so prescribing, the State Government may accept the qualifications or prescribe higher qualification but in no case prescribe any qualification less than the qualifications prescribed by the Central Government under sub-section (4) of Section 213 of the Act. In the latter event, i.e., prescribing lesser qualifications, both the rules cannot operate without colliding with each other. When the rules made by the Central Government under Section 213(4) and the statutory rules made under proviso to Article 309 of the Constitution are construed harmoniously, there is no incompatibility or inconsistency in the operation of both the rules to appoint fit persons to the posts or class of officers of the State Government vis-a-vis the qualifications prescribed by the Central Government under sub-section (4) of Section 213 of the Act.”

49. In the facts of the case at hand, the judgment in **S. Satyapal Reddy** (Supra) is completely distinguishable and the ratio does not have any relevance herein. The said judgment dealt with the provisions of the Motor Vehicle Act, 1988 wherein the power of the Central Government under Section 213(4) was to prescribe ‘minimum qualification.’ As discussed, the State Government also has powers to regulate the functioning, therefore, the field was open for the State Government to prescribe the higher educational qualification, if it deems it necessary. As such, the words ‘minimum qualification’ do not have any necessary implication on

the State, which cannot prescribe the higher educational qualification for the post of Motor Vehicle Inspector. In the said context, this Court found that when the 'minimum' prescribed qualification by the Central Government i.e., the diploma in the Mechanical Engineering and the qualification prescribed by the State Government i.e., degree in Mechanical Engineering is merely a degree in the same subject, it does not have any repugnancy on the issue. Therefore, the said judgment is of no help to the appellants.

50. In our view, the findings recorded by the High Court, *inter-alia* observing that in the context of the D&C Act for the purpose of prescribing the qualification for the Inspectors i.e., DI/DCO, the field is occupied by the Drugs Rules. The rules framed by the State Government under the proviso to Article 309 of the Constitution of India by adding experience in addition to the qualification prescribed by the Drugs Rules cannot be made applicable for their appointment as Inspectors. Similar analogy shall follow in the case of State of Karnataka, therefore, we are not impressed by the arguments as advanced on behalf of the State of Haryana as well as the State of Karnataka. As such, the arguments stand repealed, upholding the reasoning arraigned by both the High Courts.

51. Yet another point for consideration is based on the minority view of Hon'ble Judge of the High Court of Punjab and Haryana at Chandigarh, which refers to Rules 51 and 52 of the Drug Rules, corresponding to the qualifications specified in Rules of 2018 and the same requires emphasis. In the said context, it is necessary to reproduce Rule 51 which deals with '*duties of Inspectors of premises licensed for sale*' and Rule 52 which deals with '*duties of Inspectors specially authorised to inspect the manufacture of drugs*' as specified by the Drugs Rules. Both the rules refer to schedule C and C1 of the D&C Act, therefore, the same are reproduced as thus:-

“51. Duties of Inspectors of premises licensed for sale.

Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorized to inspect premises licensed for the sale of drugs-

(1) *to inspect [not less than once a year] all establishments licensed for the sale of drugs within the area assigned to him;*

(2) *to satisfy himself that the conditions of the licenses are being observed;*

(3) *to procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the Act or rules thereunder;*

(4) *to investigate any complaint in writing which may be made to him;*

(5) to institute prosecutions in respect of breaches of the Act and rules thereunder;

(6) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority;

(7) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act;

(8) when so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

52. Duties of Inspectors specially authorized to inspect the manufacture of [drugs]

Subject to the instructions of the controlling authority it shall be the duty of an Inspector authorized to inspect the manufacture of [drugs]

(1) to inspect [not less than once a year], all premises licensed for manufacture of [drugs or cosmetics] within the area allotted to him to satisfy himself that the conditions of the license and provisions of the Act and rules thereunder are being observed;

(2) in the case of establishments licensed to manufacture products specified in Schedules C and C (1) to inspect the plant and the process of manufacture, the means employed for standardizing and testing the [drugs or cosmetics], the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product;

(3) to send forthwith to the controlling authority after each inspection a detailed report indicating the conditions of the license and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed;

- (4) to take samples of the [drugs or cosmetics] manufactured on the premises and send them for test or analysis in accordance with these rules;
- (5) to institute prosecutions in respect of breaches of the Act and rules thereunder.

[SCHEDULE C

(See rules 23, 61 and 76 and Part X)

BIOLOGICAL AND SPECIAL PRODUCTS

1. Sera.
2. Solution of serum proteins intended for injection.
- [3. Vaccines for parenteral injections.]
4. Toxins.
5. Antigen.
6. Antitoxins.
7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases.
8. Insulin.
9. Pituitary (Posterior Lobe) Extract.
10. Adrenaline and Solutions of Salts of Adrenaline.
- [11. Antibiotics and preparations thereof in a form to be administered parenterally.]
- [12. Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which-
 - (a) requires to be stored in a refrigerator; or
 - (b) does not require to be stored in a refrigerator.]
13. Sterilized surgical ligature and sterilized surgical suture.
- [14. Bacteriophages.]
- [15. Ophthalmic preparations.]
- [16. Sterile Disposable Devices for single use only.]

[SCHEDULE C (1)

(See Rule 23, 61 and 76)

OTHER SPECIAL PRODUCTS

1. *Drugs belonging to the Digitalis group and preparations containing drugs belonging to the Digitalis group not in a form to be administered parenterally.*
2. *Ergot and preparations containing Ergot not in a form to be administered parenterally.*
3. *Adrenaline and preparations containing Adrenaline not in a form to be administered parenterally.*
4. *Fish Liver Oil and preparations containing Fish Liver Oil.*
5. *Vitamins and preparations containing any vitamins not in a form to be administered parenterally.*
6. *Liver extract and preparations containing liver extract not in a form to be administered parenterally.*
7. *Hormones and preparations containing Hormones not in a form to be administered parenterally.*
8. *Vaccine not in a form to be administered parenterally.*
- [9. *Antibiotics and preparations thereof not in a form to be administered parenterally.*]
- [10. *In-vitro Blood Grouping Sera.*
11. *In-vitro Diagnostic Devices for HIV, HbsAg and HCV.]*

52. After reading the above provisions, the duties in brief specified for the Inspectors under Rules 51 and 52 of the Drug Rules are reproduced in tabular form as under:-

Basis	Duties of Inspectors under Rule 51	Duties of Inspectors under Rule 52
Nature of Authorisation	Inspector authorised to inspect premises licensed for the sale of drugs	Inspector specially authorised to inspect the manufacture of drugs or cosmetics

Premises Subject to Inspection	Establishments licensed for the sale of drugs within the area assigned	Premises licensed for manufacture of drugs or cosmetics within the area allotted, as specified in Schedule C and C(1)
Requirement of experience	No experience requirement prescribed for discharge of duties under Rule 51	Authorisation contingent upon experience as prescribed in the proviso to Rule 49, namely experience in manufacture, testing, or inspection of Schedule C substances

53. In reference to the above, and on reading Rule 49 of the Drugs Rules, it is luculent that a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a University as prescribed can be appointed as Inspector under the D&C Act. Such Inspector shall exercise all duties as specified in Rule 51 of the Drugs Rules. The proviso to Rule 49 makes a distinction in the discharge of the duties of the Inspectors, whereby an Inspector having not less than 18 months of experience in the manufacture of at least of one of the substances specified in Schedule C; or has experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing

authority; or who has gained experience of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspector shall be authorised to inspect the manufacture of the substances mentioned in Schedule C. Therefore, the intent of the central law and the rules thereunder is clear. Possessing an experience of a specific nature shall not be included within the qualification prescribed for initial appointment as Inspector. It carves out a distinction between the Inspector appointed at the initial stage and the Inspectors who have gained experience as prescribed, enabling them to discharge a higher degree of responsibility by virtue of their experience.

54. In the said context, in our view, the minority opinion in reference to Rules 51 and 52 of the Drug Rules, by giving a distinct analogy, does not appear to be plausible or acceptable to this Court. Therefore, under the D&C Act, as apparent from the history and discussion appreciated by us hereinabove, the power to prescribe the qualification for Inspectors is with the Central Government. By virtue of the Drug Rules, the qualification for appointment of Inspector has been prescribed, with further distinction in the duties to be discharged by the Inspectors

appointed initially and by those after gaining experience. Therefore, the proviso to Rule 49 only deals with such distinction of the duties and does not say anything on the qualification required for appointment to the post of Inspector. Thus, Rules framed in exercise of the power under proviso to Article 309 of the Constitution of India by the State Government, or under a State statute which applies in general, prescribing distinct qualifications under the enactment, cannot override the provisions of the Drug Rules.

55. After perusal of the contents of the advertisement issued by the State of Haryana, it reveals that in addition to the educational qualification prescribed under Rule 49 of the Drugs Rules which is similarly specified in the Rules of 2018, it is contended that the candidates who applied for the post of DI/DCO may not be eligible unless they possess the experience as enumerated in the Rules of 2018. If we look into the advertisement issued by the State of Karnataka whereby, they have added experience in the nature of 'minimum' qualification. Therefore, by virtue of the Rules of 2018 or the Rules of 2013, the States of Haryana and Karnataka have made the qualification of experience a 'minimum qualification', which under Drug Rules, was prescribed only for Inspectors for the

purpose of inspection under Rule 52. In our view, such recourse is contrary to the central law i.e., the D&C Act which is primary in nature. It is further required to be observed that on conjoint reading of Section 103 of the GOI Act and Article 372 of the Constitution of India, if the respective States wish to derive power for prescribing the qualification for appointment of Inspector, they may take the recourse as permissible by way of making an amendment in the D&C Act, as made by the State of Maharashtra for certain provisions. In absence of such amendment or repeal, adding experience as prescribed in the respective State Rules as 'minimum qualification' for appointment to the post of DI/DCO is completely inconsistent with the recourse permissible. Further, when the subject was already occupied by the primary legislation, therefore, such recourse may not be countenanced under the law.

56. In view of the above, it is concluded that the powers so exercised either by the State of Haryana or Karnataka to prescribe such qualifications for appointment of Inspector, over and above the provisions of the Drug Rules, is completely alien, in particular when the subject was already occupied by the Central Government and the rules have been framed by it. Once it has been held that State Governments do not have the power to legislate on the issue

in the manner as done, and the recourse as permissible has not been taken, the question of repugnancy is not required to be dealt with. In such view of the matter, we are of the considered opinion that the High Court of Punjab and Haryana at Chandigarh or the High Court of Karnataka at Bengaluru have interpreted the provisions in right earnest and rightly allowed the writ petitions filed by the participants, assailing the addition of experience as an essential qualification to participate in the process of selection. Therefore, the question nos. (i) and (ii) are answered accordingly.

Question No. (iii)

The relevant challenge, reliefs, events with respect to the appeals arising from the State of Haryana

57. Referring to the facts in the appeals from the State of Haryana, the HPSC issued an advertisement for appointment of 4 posts of DCO, which was later increased to 26 *vide* corrigendum dated 04.06.2019. The essential qualification prescribed in the advertisement was in terms of the Rules of 1989, as substituted by the Rules of 2018, wherein experience was added within the essential qualification.

58. The recruitment test was conducted and the result was announced on 12.12.2019, however since the number of qualified candidates was less than three times the posts advertised, a second result was declared on 04.06.2020. Thereafter, the screening and process for verification of documents of the candidates was done. It may be noted that neither list included the names of the private Respondents herein nor Parveen Kumar¹² in due to lack of experience which was prescribed as an essential qualification.

59. On 07.07.2020, the HPSC *vide* an announcement rejected the candidature of participants in both lists, including the private Respondents, for non-submission of hard copy of the online application and various other reasons. Challenging the same, one Krishan Kumar, private Respondent herein, filed a representation which came to be rejected by the HPSC on 14.07.2020. In the interregnum, various private Respondents filed different writ petitions before the High Court alleging that the qualifications mentioned in the advertisement were in contravention to those prescribed under the Drug Rules, and all such connected matters were finally decided in terms of the impugned judgment herein.

¹² Appellant in Diary No 1909 of 2024.

60. Ultimately, on 18.09.2020, the HPSC declared the result for the posts as advertised, which was subject to the final outcome of the writ petitions pending before the High Court. In furtherance of the same, a letter was issued to the Additional Chief Secretary, Health Department, Government of Haryana recommending issuance of appointment orders to the successful candidates, subject to final outcome of the pending writ petitions. On 22.09.2020, the High Court in CWP No. 15067 of 2020 filed by one of the private Respondents i.e., unsuccessful candidates, granted a stay on the further recruitment process, and as such, appointment orders were not issued.

61. It may be noted here that one of the candidates filed CWP No. 16961 of 2019, which was dismissed by the Single Bench of the High Court on 04.03.2020 observing that the nomenclature of the post was changed from Drug Inspector to Drug Control Officer, with the qualification remaining as was prescribed. Challenging this order, multiple LPAs and Writ Petitions were filed before the Division Bench of the High Court, which were decided collectively *vide* the judgement dated 09.09.2022 impugned herein.

62. The High Court, by a larger Bench, upon consideration of the matter in the impugned judgment dated 09.09.2022, examined the

extent of the State Government's power to prescribe qualifications for appointment to the post of DCO in exercise of powers under the proviso to Article 309 of the Constitution of India. It proceeded on the premise that recruitment to the post is primarily governed by the D&C Act and the Drug Rules framed thereunder by the Central Government. While it was noted that the experience referred to in the proviso to Rule 49 of the Drugs Rules is relevant in the context of duties involving inspection of manufacture of substances specified in Schedule C under Rule 52. The conjoint reading of the majority and minority opinion ultimately concludes that such experience could not be elevated to be an essential qualification for initial appointment by the State in rules framed under Article 309 of the Constitution of India. It was observed that the State's power under the proviso to Article 309 of the Constitution of India extends to regulation of recruitment and conditions of service, including prescription of qualifications, subject to the constitutional limitation that such rules must not be inconsistent with the Central statute and the Rules framed thereunder, and that in the event of any conflict, the Drugs Rules would prevail over the State Rules of 2018.

63. Ultimately, the advertisement in question, and selection made pursuant to the same, was set aside by the High Court. The writ petition filed by the sole appellant Parveen Kumar was also disposed of by the Single Judge of the High Court *vide* judgement dated 30.09.2022, in terms of the judgement dated 09.09.2022 of the Full Bench of the High Court. When the matter travelled up to this Court, leave was granted on 13.03.2023, and on 17.07.2023, it was directed that on consideration of shortage of persons for the post in question, the HPSC may allow conditional appointment of persons selected, for the 26 posts as per the advertisement, but it shall be subject to final outcome of the present appeals.

The relevant challenge, reliefs, events with respect to the appeal arising from the State of Karnataka

64. Reverting to the facts in the appeal arising from Karnataka, admittedly KPSC issued the recruitment notification dated 23.03.2018 inviting applications for 83 posts of Drugs Inspectors. The eligibility criteria were prescribed in terms of KSCSA and rules framed thereunder. Written examinations were conducted and all the appellants as well as private respondents participated in the examination. On the basis of marks obtained in the written examination, first list dated 07.11.2019 of 232 eligible candidates

for interview was issued by KPSC, followed by list dated 13.11.2019 of candidates for document verification.

65. The document verification commenced from 16.11.2019, however, as contested by KPSC, they faced certain difficulties in verifying the experience certificate of certain candidates who possessed certificates from other States. To remedy the same, the interview was postponed and a Technical Committee comprising of two Assistant Drug Inspectors and one Assistant Drugs Controller was constituted to verify the experience certificates. The Committee submitted a report dated 12.11.2020, on the basis of which, only 43 candidates in addition to those already interviewed were called for interview on 27.11.2020, while excluding others on the pretext that they did not possess requisite experience, including private respondents herein.

66. Aggrieved, the private respondents (32 in total) along with unsuccessful candidates (34 in total) approached KSAT in a bunch of original applications *inter-alia* seeking to quash the list dated 27.11.2020 and praying to induct their name in the new list of candidates for interview. Pending original applications, provisional list of 66 selected candidates was published by KPSC on 15.12.2020, which was stayed by KSAT on 19.01.2021. However,

KSAT *vide* common order dated 12.05.2021 dismissed all the original applications, while granting limited relief to 5 candidates to get their documents re-verified and in case found eligible, they be considered for interview.

67. Dissatisfied, 18 unsuccessful candidates assailed the order of KSAT before High Court in the writ petition bearing No. 10575/2021. During pendency of which, KPSC in compliance of order passed by KSAT conducted interview of one candidate and thereafter published final list dated 22.06.2021 of 67 successful candidates. The recruitment process was stayed by High Court *vide* order dated 24.06.2021, however, the final list was published in the gazette on 13.07.2021. Be that as it may, concerned with the litigation, the successful candidates (appellants herein) got themselves impleaded before the High Court, whereafter, the impugned order was passed on 31.03.2023 allowing the writ petition, setting aside the common order passed by KSAT and declaring the qualification of prescribed experience in terms of KCSCA as ultra vires Section 33(2)(b) of the D&C Act read with Rule 49 of the Drug Rules. The KPSC was directed to re-do the select list within a span of three months. The High Court concluded that the State does not hold legislative competence to

prescribe an additional experience criterion for the statutory post of Drug Inspector, which is exclusively occupied by Central legislation.

68. After perusal of the proceedings of this case, it is vividly clear that *vide* order dated 17.07.2023, this Court allowed the conditional appointment of those who have been selected by the Haryana Public Service Commission on 26 posts, subject to final outcome of the present appeals. It was clarified that such condition should be incorporated in the appointment orders to be issued by the State Government, and in furtherance to such order, appointments were made but details of the same are not available on record. While in the State of Karnataka, the appointments have not been made because of the order granting stay by the High Court, and finally allowing the writ petitions. It is relevant to note that *vide* order dated 26.02.2024 in the proceedings related to Karnataka, the interim relief granted on 24.07.2023¹³ was modified to the extent that as per the directions issued in para 82(vi) of the impugned order, the respondents are permitted to redo the select list, however it shall not be finalized without leave of this Court. On the same day, the matters pertaining to the State of

¹³ Notice and stay on Para 82(vi) of the impugned order.

Karnataka was tagged with the batch of appeals arising from the State of Haryana.

69. In view of the appreciation of the facts and law, as made on issue Nos. (i) and (ii), it is apparent that the State Governments do not have power to legislate on the field except in the manner so prescribed, hence, the judgments passed by both the High Courts are upheld. At this stage, it is to be noted that the High Court of Punjab and Haryana at Chandigarh *vide* the impugned judgement dated 09.09.2022 has set-aside the advertisement and the entire process of selection and appointment to the post of Drug Inspector, whereas *vide* the impugned order, the High Court of Karnataka at Bengaluru has set-aside the order of KSAT and declared the condition prescribing experience as an essential qualification as *ultra vires*, with direction to KPSC to re-do the selection list.

70. On the insistence of the State of Haryana, this Court *vide* order dated 17.07.2023 allowed conditional appointment of the persons selected by HPSC, subject to outcome of these appeals. In furtherance, some persons have been appointed in the State of Haryana in view of liberty granted, and hence it is prayed that discretion under Article 142 of the Constitution of India be exercised in favour of those appointees. Considering the aforesaid

and the fact that the issue of adding the experience as an essential qualification before both the High Courts and in both the appeals is the same, therefore, in order to maintain consistency of the directions, we are inclined to mould the relief.

71. Accordingly, the appeals filed by the State of Haryana and arising from State of Karnataka fail, and are hereby dismissed. The appeal bearing Diary No. 1909 of 2024 filed by the sole appellant Parveen Kumar succeeds, and is hereby allowed. Accordingly, these appeals are disposed of in terms of the following directions:-

- (i) The Public Service Commission of the respective States are directed to complete process of selection by taking qualification as prescribed in Drug Rules as essential, ignoring the requirement of experience as prescribed in terms of State Rules. Thus, the qualifications specified in the respective advertisements, as an essential requirement/experience for appointment by way of additional qualification stand quashed as *ultra vires* to D&C Act.
- (ii) The Haryana Public Service Commission (HPSC) and the Karnataka Public Service Commission (KPSC) are directed to re-draw the selection list of all those candidates who possess the qualification as directed hereinabove in direction (i) and

prepare the final selection list, following the Rule 49 of the Drug Rules.

- (iii) We make it clear that if the persons appointed in the State of Haryana fall within the merit of the said newly drawn selection list, which would consequently be prepared by HPSC and KPSC respectively, in compliance with the directions hereinabove, they be continued in service without any hindrance and shall be entitled to all consequential benefits similar to the other selected candidates who find place in the newly drawn selection list.
- (iv) With respect to persons appointed in the State of Haryana, despite the selection itself being quashed; it is clarified that such appointees who do not fall within the merit of the said newly drawn selection list, the State Government shall be at discretion to continue them in employment, however only upon creation of supernumerary posts for them and not against the advertised vacancies. Simultaneously, their seniority and other benefits be decided by putting them in bottom of the select list or by taking the recourse as permissible under law.

(v) In consequence of dismissal of the Civil Appeal Nos. 1725-1731 of 2023, 1732-1738 of 2023; and Special Leave Petition (C) Nos. 16490-16491 of 2023, and further, appeal bearing Diary No. 1909 of 2024 filed by sole appellant being allowed in terms of the directions as issued hereinabove; the HPSC and KPSC are directed to prepare the final merit lists of selected candidates for the respective States within a period of eight weeks and the same be sent to the States. The respective State Government, after completing necessary formalities, shall take steps for appointment of the selected candidates within a period of eight weeks thereafter.

72. Pending application, if any, shall stand disposed of.

.....**J.**
[J.K. MAHESHWARI]

.....**J.**
[VIJAY BISHNOI]

New Delhi;
13th January, 2026.