IN THE HIGH COURT OF HIMACHAL PRADESH, SHIMLA

CWP No.4334 of 2025
Reserved on: 18.06.2025
Decided on: 30.06.2025

Biogenetic Drugs (P) Ltd. & another ... Petitioners

Versus

State of Himachal Pradesh & others ... Respondents

Coram

Hon'ble Mr. Justice Ajay Mohan Goel, Judge.

Whether approved for reporting?Yes

For the petitioners	:	Mr. R.S. Cheema, Senior Advocate, with Ms. Tanu Bedi,Advocate (through V.C.), with M/s Ananya Verma and Ajay Thakur, Advocates.
For the respondents	:	Mr. Anup Rattan, Advocate General, with Ms. Swati Draik, Deputy Advocate General, for respondents No.1 and 2-State. M/s Feery Sofat and Abhinav Ghabroo, Advocates, for respondent No.3. Mr. Janesh Mahajan, Advocate, for respondent No.4.

Ajay Mohan Goel, Judge

By way of this petition, the petitioners have, *inter alia,* prayed for the following reliefs:-

> "a*) To issue a Writ in the nature of Mandamus/Certiorari or any other appropriate writ/order/direction to set aside/quash action of respondents i.e. Seizure order/inspection report dated 12-5-2024 (Annexure P/1); memo of recovery dated 12.05.2024 Annexure P/1A),*

Seizure order/inspection report dated 9/10-5-2024 (Annexure P/2), memo of recovery dated 10.05.2024 (Annexure P/2A); and Seizure order/memo of recovery dated 12-4-2024 (Annexure P/3) vide which medicines manufactured by the petitioners containing tramadol and alprazolam along with their raw materials has been seized in gross violation of Fundamental Rights and Constitutional Right of the petitioners under Article 14, 19, 21 and the Article 300A respectively of the Constitution of India; and

b) To issue an order/writ in nature of mandamus directing the concerned respondents to release the unlawfully and unauthorizedly seized material forthwith, as the same were lawfully and properly manufactured and are the legit property of the petitioners; and

c) To issue writ/order/direction in the nature of Mandamus or any other appropriate writ/direction as deem fit by this Hon'ble Court to declare Instructions/SOP-Standard Operating Procedure Annexure P-4 passed by State Drug Controller, Himachal Pradesh ultra vires, non est, invalid, having no force of law as the same has been issued beyond the executive competence and without any statutory support, besides being violative of fundamental rights."

2. When the matter was listed on 17.06.2025, the following order was passed:-

"*Reply to the petition stands filed by the respondents.*

Learned Senior Counsel for the petitioners on instructions submits that the petitioners do not intent to file any rejoinder to the said reply(s). The arguments in the case have been restricted to the relief clause (C) i.e. the validity of the Standard Operating Procedure (Annexure P-4) issued by State Drug Controller.

Heard Mr. R.S. Cheema, learned Senior Counsel appearing for the petitioners as also learned Advocate General as well as learned counsel for the other respondents.

List for continuation on 18.06.2025."

Accordingly, the arguments have been heard on behalf of the parties on relief Clause-C only and as prayed for, the petitioners may seek the other reliefs prayed in the writ petition, before the appropriate Fora, as advised.

3. The petitioners claim to be the Pharmaceutical Companies based in the State of Himachal Pradesh. Their grievance, which is relevant for the purpose of adjudication of this writ petition, which stands confined to Clause-C, is that they are being pointed as accused qua commission of offices under the provisions of the Narcotic Drugs and Psychotropic Substances Act, 1985, because of alleged violation of a Standard Operating Procedure (hereinafter to be referred as "SOP"), dated 04.06.2021, copy whereof is appended with the writ petition as Annexure P-4, which as per the petitioners

has been issued by the State Drug Controller without any statutory backing or sanction to issue the said SOP.

4. The SOP requires, *inter alia,* sending information of sale of psychotropic substance to the Superintendent of Police and other Authority of the State/District where the purchaser is located and as per the petitioners, though the State Drug Controller has no power to incorporate such conditions either under the Drugs Control Act or the Drugs Control Rules, yet an attempt has been made to create a legal justification by making a reference to the notification of the Central Government dated 11.02.2020, enforced on 01.03.2021 in the same.

5. Learned Senior Counsel for the petitioners argued that the impugned SOP has no legal force and as the issuance thereof is without any statutory backing, reliance thereupon by the Authorities to unduly harass the petitioners is completely unjustified. Learned Senior Counsel argued that the SOP, i.e. Office Order dated 04.06.2021, is neither a Statutory Notification, nor a Statutory Regulation and neither the Drugs and Cosmetics Act nor the Rules framed thereunder, confer any such power upon the State Drug Controller to issue any such Office Order. He submitted that as the issuance of the Office Order/SOP is an act which amounts to overreaching the Drugs and Cosmetics Act, 1940 (hereinafter to be

referred as 'the 1940 Act') and the Rules framed thereunder, the Office Order being without any statutory backing, needs to be quashed and set aside.

6. Learned Senior Counsel took the Court through Office Order dated 04.06.2021 and submitted that an impression has been given therein that the issuance of the same was necessitated by a Notification issued by the Ministry of Health and Family Welfare appended with the writ petition as Annexure 4-A, dated 11.02.2020. Learned Senior Counsel submitted that however, a perusal of this Notification would demonstrate that the same did not warrant issuance of any such Office Order/SOP and, therefore also, issuance of the said Office Order/SOP in the garb of the Notification of the Central Governemnt is *per se* bad in law.

7. Learned Senior Counsel also referred to the relevant Sections of the 1940 Act and the Rules framed thereunder, which will be referred to by me in detail hereinafter and submitted that the manufacturing as well as the subsequent sale of the drugs being manufactured by the petitioners is duly controlled by the said provisions and as the Act and the Rules are a complete Code in themselves, which contain all do's and don'ts, the additional SOP being imposed upon the petitioners by the State Drug controller, without any authority in law to issue the same, is *per se* bad.

Accordingly, learned Senior Counsel prayed that the petition be allowed and the impugned Office Order/SOP (Annexure P-4), dated 04.06.2021, be quashed and set aside.

8. On the other hand, learned Advocate General justified the issuance of SOP by submitting that the same was not only issued in the larger public interest to control the menace of drug abuse and to ensure that the drugs manufactured by the Companies like the petitioners, did not land in wrong hands. The issuance of the SOP was in exercise of the powers conferred upon the State Drug Controller/Licensing Authority under Sections 18B and 22 of the 1940 Act. Learned Advocate General with vehemence submitted that Section 18B and Section 33 (2)(e) and (ee) of the 1940 Act did confer the authority upon the Officer concerned to issue the SOP so that the activities being carried out by manufacturers like the petitioners can be monitored and, therefore, as there is no merit in this writ petition, the same be dismissed.

9. In rebuttal, learned Senior Counsel for the petitioners, *inter alia,* while reiterating the submissions made on behalf of the petitioners, argued that the submissions made by the learned Advocate General were beyond the pleadings. By referring to the contents of Para Nos. 7 and 8 of the writ petition as also reply filed thereto by the State, learned Senior Counsel submitted that the only

defence taken in the reply by the State, to the contention of the petitioners that the SOP was issued without any Statutory backing, was that the same was issued in larger public interest and there was nothing mentioned therein as to under which provision of law the same was issued. Learned Senior Counsel reiterated that the 1940 Act and Rules framed thereunder do not authorize State Drug Controller to issue any such SOP.

10. I have heard learned Senior Counsel for the petitioners as well as learned Advocate General. I have also heard learned counsel appearing for the other respondents.

11. The petitioners have appended collectively as Annexure P-5, the Drugs and Manufacturing Licences issued to them and Product Permissions. The moot issue for the purpose of adjudication of this writ petition is in a very narrow premise. The same is whether the State Drugs Controller has any Authority in law to issue the impugned Office Order/ SOP or not.

12. The Drugs and Cosmetics Act, 1940 has been brought into force to regulate the import, manufacturing, distribution and sale of drugs and cosmetics.

13. Section 2(b) of the 1940 Act defines as under:-

> "*(b) "drug' includes-*
>
> *(i) all medicines for internal or external use of human*

beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board."

14. Chapter IV of the 1940 Act deals with manufacture, sale and distribution of Drugs and Cosmetics. Section 33 of the Act, which is part of Chapter IV confers power upon the Central Government to make Rules to give effect to the provisions of Chapter IV of the 1940 Act.

15. Clause (e) of sub-section (2) of Section 33 of the 1940 Act, provides as under:-

> "*(e) prescribe the forms of licences for the manufacture for sale or for distribution), for the sale and for the distribution of drugs specified drug or class of drugs for of cosmetics or any specified cosmetic or class of cosmetics], the form of application for such which such licences may be 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.*"

Clause (e) of sub-section (2) of Section 33 of the 1940 Act, provides as under:-

> "*(ee) prescribe the records, registers or other documents to be kept and maintained under section 18B*"

16. Before proceeding further, at this stage, it is relevant to refer to Section 18 of the Act, which prohibits the manufacture and sale of certain Drugs and Cosmetics in terms of the provision of said Section, except under and in accordance with the condition of a License issued for such purpose under Chapter IV of the Act.

17. Section 18 of the Act reads as under:-

> "***18**. Prohibition of manufacture and sale of certain drugs and cosmetics.— From such date as may be fixed by the*

State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(ii) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities, thereof;

(iv) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any

of the provisions of this Act or any rule made thereunder;

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality."

18. Section 18B of the Act, which provides for maintenance of records and furnishing of information, reads as under:-

"**Section *18B***. *Maintenance of records and furnishing of information-Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.*"

19. In the present case, as it is not an allegation against the petitioners that they are manufacturing any Drug without having a licence to do so, this Court is not dwelling upon this aspect of the matter. Further, as it is not an allegation against the petitioners that though they have a Licence to manufacture a Drug, but they are manufacturing the same in violation of the Manufacturing Licence issued to them, therefore, this Court is not dwelling upon that aspect of the matter also. All that this Court shall be answering is the issue, weather the Office Order issued by the State Drug Controller is a valid Office Order or not. Meaning thereby, that the same has been issued by the Authority under Authority in law to issue the same or not. Therefore, this Court shall not be dwelling upon any other issue, more so, in the light of the fact that the other issues which have been raised in the writ petition, have been left open to be raised before the appropriate Fora.

20. Whereas, the contention of the learned Senior Counsel for the petitioners is that the Office Order/SOP issued by the State Drug Controller, is without any authority in law, learned Advocate General argued that the same has been issued in larger public interest and in exercise of powers conferred under Sections 18B and 22 of the Act. No other point was urged on behalf of the

respondents to justify the source of authority vested in the State Drug Controller to issue this Notification.

21. Therefore, now this Court will dwell upon the issue, as to whether Sections 18B and 22 of the Act confers any such power upon the State Drug Controller to issue the impugned Office Order and whether the impugned Office Order was necessitated by the issuance of the Notification issued by the Central Government, as it finds mention in the impugned order or not.

22. The Notification of the Central Government referred to in the impugned Office Order is dated 11.02.2020. Copy of this Notification is appended with the petition as Annexure P-4A. For ready reference this Notification is being reproduced hereinbelow:-

> *"G.S.R. 101 (E). Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required under sub-section(1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 447(E), dated the 24th June, 2019, in the Gazette of India, Extraordinary, Part 11, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on*

which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on the 24th June, 2019;

And whereas objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

(1) These rules may be called the Drugs and Cosmetics (Amendment) Rules, 2020.

(2) They shall come into force on the 1st day of March, 2021. 2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 2,-

(6) existing clause (ea) shall be re-lettered as clause (eb), and before clause (eb) as so re-lettered, the following clause shall be inserted, namely:-

"(ea) "Marketer" means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his

name on the label of the drug with a view for its sale and distribution;';

(ii) existing clauses (ea) and (eb) shall respectively be re-lettered as (eb) and (ec).

3. In the said rules, after rule 84C, the following rules shall be inserted, namely:-

"84D. Agreement for marketing. No marketer shali adopt any drug manufactured by another manufacturer for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution without an agreement as referred to in clause (ea) of rule 2.

84E. Responsibility of marketer of the drugs. Any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules.".

4. In the said rules, in rule 96, after sub-clause (xii) of clause (1), the following sub-clause shall be inserted, namely:-

"(xiii) The name of the marketer of the drug and its address, in case the drug is marketed by a marketer: Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown."

23. A perusal of this Notification demonstrates that the Central Government in exercise of powers conferred under Sections 12 & 13 of the 1940 Act, after consultation with the

Drugs Technical Advisory Board, amended the Drugs and Cosmetic Rules, 1945, as mentioned in the Notification. There is no mention in this Notification that for the purpose of giving effect to the amendments carried out in the said Notification, any Office Order or SOPs, are required to be issued by the respective State Drug Controllers. Further, perusal of the Notification demonstrates that the amendments incorporated therein are to the effect that certain Clauses were to be re-lettered and Clause (ea) was to be inserted in Rule 2 and after Rule 84C, Rules 84D & 84E were to be inserted. Similarly, in Rule 96 also, a Sub-Clause was to be inserted. When we peruse the said Notification harmoniously with the impugned Office Order, besides the fact that there is no mention in the Statutory Notification of issuance of any SOP for implementation thereof, one finds that the amendments carried by way of Notification Annexure P-4A, are otherwise also alien to the contents of the SOP, which otherwise purportedly has been issued to implement Notification dated 11.02.2020.

24. As already observed hereinabove, the main argument of the learned Advocate General was that Section 18B of the 1940 Act conferred jurisdiction upon the State Drug Controller to issue the SOP. Section 18B of the Act has already been quoted by me

hereinabove. This Section provides that every person holding a License under Clause (c) of Section 18 of the Act shall keep and maintain such records, registers under the documents, as may be prescribed and shall furnish to any Officer or Authority, exercising any power of discharging any function under this Act, such information as is required by such Officer or Authority for carrying out the purposes of this Act. This is a statutory mandate.

25. Sub-Clause (ee) of sub-section (2) of Section 33 of the Act further provides that the Central Government may in the mode prescribed in Section 33 of the Act make rules in this regard and such rules may **"prescribe the records, registers or other documents to be kept and maintained under Section 18B."**

26. Therefore, it is apparent from the harmonious reading of Section 18B with Clause (ee) of sub-section (2) of Section 33 of the Act that the records, registers or other documents which are to be kept and maintained under Section 18B of the Act and have to be maintained in the mode and manner as the Rules framed by the Central Government may prescribe.

27. Similarly, in the course of arguments of learned Advocate General, in addition to Section 18B of the Act, though there was also a reference to Section 22 thereof to substantiate as to what is the source of power or Authority of the Drug Controller

to issue the impugned Office Order, however, perusal thereof demonstrates that in terms of Section 22 of the Act, power of inspection has been conferred upon any Inspector and this is specifically made subject to the provisions of Section 23 of the Act and the Rules framed by the Central Government. Therefore, it cannot be said that Section 22 of the Act confers any power upon the State Drug Controller to issue the kind of Notification which stands assailed in this writ petition.

28. Similarly, a bare perusal of Section 18B of the Act also demonstrates that no power is conferred upon the State Drug Controller to issue an Office Order/ SOP of the nature as has been issued in this case. Further, the impugned Office Order also does not state that the State Drug Controller has issued the Office Orders by exercising powers conferred either under Section 18B of the Act or Section 22 of the Act. All it says is that the Office Order has been issued to give effect to the Notification issued by the Central Governemnt and as already observed hereinabove, this Notification, in terms whereof the Central Governemnt incorporated certain amendments in the Rules framed by it, did not envisage issuance of such like Office Orders by the State Drug Controller to give effect to the Notification.

29. Besides this, a perusal of the Drugs and Cosmetics Rules further demonstrates that whereas Section 69 of the Act takes care of the application for Licence to manufacture the drugs other than those specified in Schedule-C and C (1) to the Drugs and Cosmetics Rules, Section 71 of the Act provides for condition for the grant or renewal of a Licence in Form-25 or Form 25F and similarly, Rule 74 clearly lays the conditions of Licence in Form-25 and 25F. Clause (b) of Rule 74 reads as under:-

> "*(b) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act. provided that where such further requirements are specified in the rules, these would come into force, four months after publication in the Official Gazette*."

Clause (m) of Rule 74 reads as under:-

> "*(m) the licensee, who has been granted a licence in Form 25F, shall-*
>
> *(i) forward to the licensing authority of the concerned States of manufactur4e and supply of the drugs a statement of the sales effected to the manufactures, wholesalers, retailers, hospitals, dispersaries and nursing homes and Registered Medical Practitioners every three months;*
>
> *(ii) maintain accounts of all transactions giving details as indicated Below in a register bound and serially*

page numbered and such records shall be retained for a period of five years or one year after the expiry of potency, whichever is later-

A. *Accounts of the drugs specified in Schedule X used for the manufacture-*

1. Date of issue

2. Name of the drug.

3. Opening balance of stock on the production day.

4. Quantity received, if any, and source from where received.

5. Quantity used in manufacture.

6. Balance quantity on hand at the end of the production day.

7. Signature of the person in charge.

B. *Accounts of production-*

1. Date of manufacture.

2. Name of the drug.

3. Batch Number.

4. Quantity of raw material used in manufacture.

5. Anticipated yield.

6. Actual yield.

7. Wastage.

8. Quantity of the manufactured goods transferred.

C. *Accounts of the manufactured drugs-*

1. Date of manufacture.

2. Name of the drug.

3. Batch Number.

4. Opening Balance.

5. Quantity manufactured.

6. Quantity sold.

7. Name of the purchaser and his address.

8. Balance quantity at the end of the day.

9. Signature of the person in charge."

30. Therefore, it is apparent and evident from the said provisions that the Act and the Rules take care of everything including the furnishing of information qua supply of drug as well as sales effected. Any non-compliance or breach thereof is punishable in terms of the provisions of the Drugs and Cosmetics Act, 1940, which is both a substantive and a procedural law.

31. In this view of the matter, when the Rule making power is exclusively conferred upon the Central Government and the Central Governemnt has in exercise of the powers so conferred , framed Rules which govern all the activities of manufacturers like the petitioners including the sale of drug manufactured, the Office Order in question which has been issued by the State Drug Controller, bereft of any Authority in law vested in the State Drug Controller to issue the same, is not sustainable in the eyes of law.

32. At this stage, this Court would like to refer to the pleadings of the parties. In Paras 7 and 8 of the writ petition, the petitioners have taken a specific stand that the Office Order/SOP, dated 04.06.2021, issued by the State Drug Controller has been

issued without any statutory backing or sanction to issue the said SOP. It is specifically mentioned that neither the Drugs and Cosmetics Act, 1940 nor the Rules framed thereunder permit the State Drug Controller to issue any Standard Operating Procedure/SOP imposing conditions therein. Reply filed by the State to these Paras of the writ petition demonstrates that it has not been specifically or othrwise stated by the State that the SOP has been issued by the State Drug Controller who had a legal mandate to issue the same. All that has been said is this that the SOP has been issued in larger public interest to implement the Gazette Notification, dated 11.02.2020.

33. As already observed hereinabove, Notification, dated 11.02.2020, does not command issuance of any SOP for implementation thereof by the State Drug Controller. Otherwise also, this is a Statutory Notification issued by the Central Governemnt carrying out amendments in the Drugs and Cosmetics Rules. The Act and the Rules are self-speaking that what are the results of the violation thereof. Therefore also, the contention of the State that the same has been issued in public interest so as to check drug abuse has no force as State Drug Controller had no power to issue the same in law.

34. In the absence of there being any legal authority vested

in the State Drug Controller to issue the impugned Office Order, the justifications given by the State Governemnt *san* any legal backing/ sanction or legal authority vested with the State Drug Controller to issue the same, cannot justify the issuance of said Office Order.

35. Accordingly, in the light of the observations made hereinabove, this writ petition is allowed to the extent that **impugned Office Order/SOP (Annexure P-4), dated 04.06.2021**, issued by the State Drug Controller is quashed and set aside on the ground that the same has been issued without any Statutory backing, executive competence or legal sanction under the provisions of Drugs and Cosmetics Act, 1940 and the Rules framed thereunder to issue the same.

35. The petition stands disposed of in above terms. Pending miscellaneous application(s), if any also stand disposed of accordingly. No order as to costs.

(Ajay Mohan Goel)
Judge

June 30, 2025
(Rishi)