IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 20.11.2019
Pronounced on : 28.02.2020

C O R A M

THE HON'BLE MR.AMRESHWAR PRATAP SAHI, CHIEF JUSTICE

a n d

THE HONOURABLE MR.JUSTICE SUBRAMONIUM PRASAD

Writ Petition No.33924 of 2017
&
Writ Petition No.4670 of 2018

WP.No.33924/2017

All India Drugs Control Officers Confederation
Building No.46, Flat 2261 "Suprabhat" CHSL
First floor, Gandhi Nagar,
Bandra (E), Mumbai - 400 051.
Maharashtra.
Rep. by its President,
Mr.M.Dhilip Kumar. ...Petitioner

Vs

1. The Government of India,
   Rep. by its Secretary to Government,
   Ministry of Health and Family Welfare,
   Room No.414-A, D-Wing, Nirman Bhawan,
   New Delhi - 110 011.

2. The Central Drugs Standard Control Organisation,
   Directorate General of Health Services,
   FDA Bhawan, ITO, Kotla Road,
   New Delhi - 110 002. ...Respondents

Prayer : Petition filed under Article 226 of the Constitution of India praying for the issuance of a writ of Declaration, to declare the impugned amendment notification issued in G.S.R 1337 (E) dated 27.10.2017 by the 1st respondent as ultra vires, unconstitutional, arbitrary and illegal.

For petitioner ... Mr.G.Sankaran
For respondent ... Mr.G.Karthikeyan, ASGI.
(for R1 & R2)

WP.No.4670/2018

The Pharmaceutical Manufacturers' Association
of Tamil Nadu,
Block D-1. Baid Mehta Complex,
16/183, Anna Salai, Little Mount,
Saidapet, Chennai - 600 015. ...Petitioner

Vs

1. Union of India,
   Rep. by its Secretary,
   Health & Family Welfare,
   Nirman Bhavan, New Delhi - 110 011.

2. The Drugs Controller General of India,
   FDA Bhawan, ITO, Kotla Road,
   New Delhi - 110 002.

3. The State of Tamil Nadu,
   Rep. by its Secretary,
   Health & Family Welfare,
   Fort St.George, Chennai - 600 003.

4. The Director fo Drugs Control,
   Office of the Drugs Controller,
   Anna Salai, Teynampet,
   Chennai - 600 018. ..Respondents

Prayer : Petition filed under Article 226 of the Constitution of India praying for the issuance of a writ of Declaration, to declare the impugned Rule 73AB, Rule 84C and Rule 143A of the Drugs and Cosmetics Rules, 1945, introduced by Drugs and Cosmetics Rules (Tenth Amendment) Rules, 2017 notified in G.S.R 1337(E) dated 27.10.2017 as ultra vires, the Drugs and Cosmetics Act, 1940 and Constitution of India and consequentially forbear the 2nd respondent from conducting joint inspection along with State Drug Licensing Authorities before grant of manufacturing licenses or conduct periodical joint inspections of drug manufacturing establishments.

For petitioner ... Mr.T.D.Selvan Babu
For respondent ... Mr.K.Raju, CGSC.
(for R1 & R2)
Mr. N.Srinivasalu
Addl.GP. for R3 & R4.

COMMON ORDER

Subramonium Prasad,J.

Writ Petition No.33924 of 2017 and Writ Petition No.4670 of 2018 filed by the All India Drugs Control Officers Confederation and the Pharmaceutical Manufacturers' Association respectively, challenge the vires of Rule 73AB, Rule 84C and Rule 143A of the Drugs and Cosmetics Rules, 1945, introduced by Drugs and Cosmetics Rules (Tenth Amendment) Rules, 2017 notified in G.S.R 1337(E) dated 27.10.2017 as ultra vires the Drugs and Cosmetics Act, 1940.

2. Since the prayer in both the writ petitions are identical, with the consent of parties the writ petitions are being disposed of by a common judgment. It is the contention of the petitioners that the Drugs and Cosmetics Rules, 1945 is a pre-Constitution law framed under a Central legislation enacted under Government of India Act, 1935. It is stated that the 1940 Act was brought in with the object to regulate the import, manufacture, sale and distribution of drugs and cosmetics. It is stated that the Act had a clear demarcation of powers between the Government of India and the Provinces, before the Constitution of India came into the force. It is stated that the same structure has been adopted after independence, keeping in mind the federal structure of the Country. According to the petitioners, the Central Government exercises its powers regarding matters relating to import of drugs and cosmetics into the country whereas the State Government exercises its powers on matter pertaining to manufacture, sale and distribution of drugs and cosmetics. It is stated that the Government of India i.e. Ministry of Health and Family Welfare as the Central Drugs Standard Control Organisation are trying to interfere in function and powers vested with the State and are interfering with the powers of the State Governments to regulate manufacture, sale and distribution of drugs and cosmetics. It is stated that the impugned notification and the new Rule introduced by the impugned notification are an affront to the powers of the State which has its control over manufacture, sale and distribution of drugs.

3. Entry 26 in List II deals with the production, supply and distribution of goods subject to the provisions of Entry 33 of List III. Entry 33 of List III deals with the trade and commerce in and the production, supply and distribution of:-
(a) the products of any industry where the control of such industry by the Union is declared by Parliament by law to be expedient in the public interest, and imported goods of the same kind as such products;
(b) foodstuffs, including edible oilseeds and oils;

(c) cattle fodder, including oilcakes and other concentrates;
(d) raw cotton, whether ginned or unginned, and cotton seed; and
(e) raw jute.

It is the contention of the petitioner that manufacture and sale of drugs and cosmetics falls within Entry 26 of List II, that is, production, supply and distribution of goods and the Central Government cannot interfere with such powers, since it is purely in the domain of the State Government. It is stated that the main thrust of the amendment brought in by the Drugs and Cosmetics Rules, 1945 in G.S.R.1337(E) dated 27.10.2017, reads as under:-

> "(i) The manufacturing and selling licences will remain valid permanently unless suspended or cancelled. There will be no need for renewal of licences every five years. However, the licensee will have to pay retention fee before expiry of license every succeeding five years from the date of issue of licence.
>
> (ii) The premises will be required to be inspected before grant of manufacturing drugs and cosmetics licences jointly by the Drugs Inspector appointed by the Central Government and the State Government.
>
> (iii) The joint inspections of the licensed premises by the Drugs Inspector appointed by the Central Government and the State Government atleast once in three years will become mandatory."

The objection is to the joint inspection by the Drugs Inspector of Central Government and State Government.

4. The two instant writ petitions have been filed by the All India Drugs Control Officers Confederation and the Pharmaceutical Manufacturers' Association. They are aggrieved by the provisions of Rules as amended, as per the impugned Notification dated 27.10.2017, requiring joint inspections by Inspectors appointed by the Central Government and State Government before grant of licence/manufacture of drugs and cosmetics and also during validity of licences as well as dispensing with the issuance of renewal of licence to both manufacture and sale licences which according to the petitioners is inconsistent that the scheme of Drugs and Cosmetics Act, 1940, having regard to the federal structure of India and well defined division of powers between Central and State Government in the Act itself. Further, according to the petitioner, the amended Rules are overreaching and surpassing the provisions of plenary legislation by making the implementation of provisions of the Drugs and Cosmetics Act ineffective, ultimately offending the object and reason of the Act. It is therefore contended that the amended Rule as notified in the impugned Notification is ex-

facie unconstitutional, ultra vires, arbitrary and illegal.

5. It is stated that the impugned amendment to Drugs and Cosmetics Rules is in violation to provisions of the Act. It is contended that, Section 21 of the Act provides for appointment of Drug Inspectors by Central Government or State Government by Notification in the official Gazette. Section 22 of the Act defines the powers of Inspectors which include inspection on licenced premises, taking samples, search and seizure and to pass orders not to dispose any stock of such drugs or cosmetics for such specified period to ascertain the violation, apart from other powers. Section 23 of the Act prescribes procedure of Inspectors on inspection and 23(5) directs that where an Inspector takes any action under clause (c) of section 22, he shall ascertain whether or not the drug or cosmetics contravenes any of the provisions of section 18 and, if it is ascertained that the drug or cosmetics does not so contravene, forthwith revoke the order under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized. Accordingly, section 23 of the Act contemplates the State Drug Inspector to ascertain the contravention of the provisions of section 18 of the Act to take further steps as per law. It is therefore submitted that, as per section 18 of the Act, the Drug Inspector appointed by State Government alone can take a action as per the procedure prescribed under section 23 (5) of the Act and the impugned amendment to the Rules ordering for joint inspection would be contrary to the relevant provisions of the Act, apart from resulting in ambiguity.

6. It is contended that when the Drug Inspector appointed by State Government is in the control of an officer appointed by the State Government (Controlling Authority) who required to carry out inspections of Controlling Authority under Rule 52. The amendment directing joint inspection will be in contravention to Rule 52 in as much as there cannot be any instruction by State Controlling Authority to Drug Inspector appointed by Central Government and the Drug Inspector appointed by Central Government cannot send the inspection report to the State Controlling Authority. It is therefore submitted that, the implementation of Rule 52 with reference to duties of Inspector authorized to inspect the premises of manufacture of drugs and cosmetics will be completely thwarted by the impugned amendment and the rules cannot be effectively implemented. It is therefore contended that a serious discrepancy is created in implementation of the provisions of existing Rules as per the impugned amendment to the Rules, notified.

7. It is submitted that Rule 85 relates to cancellation and suspension of licences clause (2) of Rule 85, stipulate that the

lincensing authority may by an order in writing stating the reasons there for, cancel licence issued under part 7 or suspend it for such period after providing opportunity to the licensee or to direct the licensee to stop manufacture, sale and distribution of the said drugs and for destruction of drugs and stock thereof, if in his opinion the licensee has failed to comply with the condition of licence or with any provisions of Act and Rules. The licensing authority has to take the decision under Rule 85(2) based on the detailed report from the Drug Inspector after inspection of the licenced premises. In the event of any joint inspection, the State licensing authority cannot issue any instructions to the Drug Inspector appointed by Central Government and no decision can be arrived by State licensing authority in the event of conflict in the reports of the State Drug Inspector and Central Drug Inspector.

8. It is contended that the amendment to the Rules prescribes joint inspection against the public interest in as much as no immediate action can be taken by State Drug Inspector for search and seizure of drug manufacturing premises contravening of the provisions of Act and Rules and to pass orders for stop manufacturing, sale or distribution on an urgent basis in an emergency situation.

9. Counters have been filed by the Government. In the counter, it is stated for the purpose of "Ease of Doing Business", a proposal for suitable amendment in the Drugs and Cosmetic Rules, 1945 was proposed, providing that the license once issued shall remain valid forever, unless suspended or cancelled by the Licensing Authority, was placed for consideration before the Drugs Technical Advisory Board (DTAB) a statutory body constituted under Section 5 of the Drugs and Cosmetics Act, 1940. The committee agreed for the proposal that the manufacturing and sale licences once issued, shall remain valid forever, unless suspended or cancelled by the Licensing Authority subject to following conditions;

- Such inspection for grant of licence shall be carried jointly by State and Central Drugs Inspectors involving relevant experts of respective area considering the category of the drug for GMP AGLP inspection.
- Further the committee recommended for one time grant of licence, the number of Drug inspectors and other regulatory officials in respective areas at the State and Central level shall be commensurate with the number of manufacturing units in specific area / jurisdiction.
- Such licensees shall be subjected to minimum of one annual inspection until unless justified otherwise on the basis

of risk evaluation.

• The observations of the inspection report shall be shared with the licensee or proposed licensee immediately after the inspection and the report of observation of the inspection shall be made available to public on website of State or Centre. The recently published checklist by CDSCO on its website after for risk based GMP inspection may be used for inspection and publication of the report.

• State wise data about manufacturing units inspected and found satisfactory, should be maintained and uploaded on the website by State and Central drug regulatory authorities involved in issue of such licences.

10. It is stated in the counter that the Ministry of Health and Family Welfare had published the notification vide G.S.R 1337 (E) date 27-10-2017 based on the recommendation made by Drugs Technical Advisory Board (DTAB). It is further submitted that G.S.R. 1337 (E) dated 27.10.2017 does not take any power from State Licensing Authority. By this notification the validity of license has been made life long without the need of renewal. Efficacy and Quality of the drugs throughout its validity. The perpetual licence will avoid the administrative obstacles like renewal of application and its licensing procedure. As the licences become perpetual, there shall be strict monitoring over the activities on industry to ensure Safety, Efficacy and Quality of drugs. This can be ensured effective by way of Joint Inspections by Central Drugs Inspectors and State Drugs Inspectors.

11. It is stated that the State Government will continue to exercise their powers as vested under the Act. It is further submitted that the manufacturing license power is still vested with concerned State Licensing Authority and there is no intention of Central Government to interfere with the functioning and power vested with State Government conferred under Chapter-IV of Drugs and Cosmetics Rules, 1945.

12. It is further stated that the said notification is in the public interest and intend to ensure the safety, efficacy and quality of the drug manufactured and sold in the country in the interest of larger public health. By this notification there is Joint Inspection for grant of licence and verification of compliance only, which results in an unique inspection procedure throughout the Country for maintaining a uniform quality compliance by the pharmaceutical industry. This notification does not interfere with the Powers of Inspectors mentioned under Section 22 and Section 23.

13. Heard the counsel for the parties.

14. The Drugs and Cosmetics Act was enacted in 1940 falling under item 19 of List III of VIIth schedule under the Government of India Act 1935. With the commencement of the Constitution of India, the same corresponds to entry 19 List III of the VIIth schedule that deals with the drugs and poison. Rules introduced by the Drugs and Cosmetics Rules (Tenth Amendment) Rules, 2017, are challenged herein, namely Rule 73AB, Rule 84C and Rule 143A. The same reads as under:-

> "73AB.Inspection for grant of licence and verification of compliance:-
>
> (1) Before a licence in Form 25 or Form 25A or Form 25B or Form 25F is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act who shall examine the establishment intended to be used or being used for the manufacture of drugs.
>
> (2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and State government to verify the compliance with the conditions of licence and the provisions of the Act and these rules not less than once in three years or as needed as per risk based approach."
>
> Rule 84C.Inspection for verification of compliance:- (1) Before a licence in Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA, is granted the licensing authority or Central Lincence Approving Authority, as the case may be, shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act who shall examine the establishment intended to be used or being used for the manufacture of drugs.
>
> (2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and State government to verify the compliance with the conditions of licence and the provisions of the Act and these rules not less than once inthree years or as needed as per risk based approach.
>
> 143A. Inspection for grant of licence and verification of compliance:-
>
> (1) Before a licence in Form 32 or Form 32A or

Form 33 is granted, the licensing authority shall cause the establishment in which the manufacture of cosmetics is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act who shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and State government to verify the compliance with the conditions of licence and the provisions of the Act and these rules not less than once in three years or as needed as per risk based approach."

15. A perusal of these three rules would show that before a licence is granted in Form 25 or Form 25A or Form 25B or Form 25F, under Rule 73AB, a joint inspection is to be conducted by the Drugs Inspectors appointed by the Central Government and the State Government, to find out whether the establishment intended to be used or being used for the manufacture of drugs, and is in accordance with the requirements or not and further the establishment compliance with the conditions of licence and the provisions of the Act.

16. Similarly, Rule 84C, provides that before a licence is granted in Form 28 or Form 28A or Form 28D or Form 28DA, a joint inspection by the Drugs Inspectors appointed by the Central Government and the State Government, be conducted to find out whether the establishment is intended to be used or is being used for the manufacture of drugs, and is in accordance with the requirements or not and further the establishment compliance with the conditions of licence and the provisions of the Act.

17. Rule 143A, provides that before a licence is granted in Form 32 or Form 32A or Form 33, a joint inspection by the Drugs Inspectors appointed by the Central Government and the State Government be done, to find out whether the establishment intended to be used or being used for the manufacture of drugs, and is in accordance with the requirements or not and further the establishment compliance with the conditions of licence and the provisions of the Act.

18. Form 25 of the Drugs and Cosmetics Rules, 1945 deals with the licence to manufacture for sale or for distribution of drugs other than those specified in [3][Schedules C,C(1) and X].

Form 25A deals with Loan [Licence to manufacture for sale or

3 Subs.by G.S.R 462(E), dated 22nd June, 1982 (w.e.f.22-06-1982]

for distribution of/ Drugs other than those specified in [4][Schedules C,C(1) and X].

Form 25B - Licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C(1) [3][Excluding those specified in Schedule X]

Form 25F - [3][Licence to manufacture for sale or for distribution of] Drugs specified in Schedule X and not specified in Schedules C and C(1)

Form 28 - [1][Licence to manufacture for sale or for distribution of] Drugs specified in Schedules C and C(1) [2][Excluding those specified in Schedule X]

Form 28A - Loan [3][Licence to manufacture for sale or for distribution of] Drugs specified in Schedule C and C(1) [4][Excluding those specified in Schedule X]

Form 28D - Licence to manufacture for sale or for distribution of [2][Large volume parenterals/SERA and Vaccine/Recombinant DNA (R-DNA) Derived Drugs] Specified in Schedule C and C(1) Excluding those specified in Schedule X.

Form 28DA - Licence to manufacture for sale or for distribution of large volume parenterals/SERA and Vaccine/Recombinant DNA (R-DNA) Derived Drugs excluding those specified under Schedule X

Form 32 - [2][Licence to manufacture cosmetics for sale or for distribution]

Form 32A - [3]Loan [Licence to manufacture cosmetics for sale or for distribution]

Form 33 - Certificate of Renewal of Licence to manufacture Cosmetics for sale.

19. Section 33 of the Drugs and Cosmetics Act, 1940 authorizes the Central Government to frame rules. Section 33(2)(a) of the Drugs and Cosmetics Act, 1940, permits rules to be framed to provide for the establishment of laboratories for testing and analysing drugs [4][or cosmetics]; Section 33(2)(e) of the Drugs and Cosmetics Act, 1940, permits to frame rules to prescribe the forms of licences [4][for the manufacture for sale or for distribution], for the sale and for the distribution of

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4 Subs.by G.S.R 462(E), dated 22nd June, 1982 (w.e.f.22-06-1982]
3 Subs.by G.S.R.462(E), dated 22nd June, 1982 (w.e.f.22-6-1982) - Form 25B
3 Subs.by G.S.R.788(E), dated 10th October, 1982 (w.e.f.22-6-1982) - Form 25F
1 Subs.by G.S.R.788(E), dated 10th October, 1982 (w.e.f.10-10-1985) - Form 28
2 Ins.by G.S.R.462(E), dated 22nd June, 1982 (w.e.f.22-6-1982) - Form 28
3 Subs.by G.S.R.788(E), dated 10th October, 1982 (w.e.f.10-10-1985) - Form 28A
4 Ins.by G.S.R.462(E), dated 22nd June, 1982 (w.e.f.22-6-1982) - Form 28A
2 Subs.by G.S.R.26(E), dated 19th January, 2006 (w.e.f.19-1-2006) - Form 28D
2 Subs.by G.S.R.788(E), dated 10th October, 1982 (w.e.f.10-10-1985) - Form 32
3 Subs.by G.S.R.788(E), dated 10th October, 1982 (w.e.f.10-10-1985) - Form 32A
4 Ins. by Act 21 of 1962, sec. 22 (w.e.f. 27-7-1964)
4 Sub. by Act 68 of 1982, sec. 29, for "for the manufacture for sale" (w.e.f. 1-2-1983)

drugs or any specified drug or class of drugs [5][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 [6][the qualifications of such authority] and the fees payable therefor; [6][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];

20. A perusal of above would show that the Central Government has the competence to pass legislation or frame any rules under Drugs and Cosmetics Act, to regulate the grant of licence. The argument of the petitioners that only the State Government can pass legislation for production, supply and distribution of goods, under entry 27 in List II, cannot be accepted. Drugs specifically fall under entry 19 List III and are out side the scope of entry 27 List II. Drugs cannot therefore fall within entry 27 of List II, which deals with production, supply and distribution of goods. Since drugs are specifically dealt with in entry 19 List III, it is specifically therefore excluded from the ambit of entry 27 List II. A provision could be held to be unconstitutional only when the legislature bringing about the legislation was incompetent to enact the provision or that it offends some provisions of the Constitution or is contrary to the principal Act under which it is framed.

21. The Hon'ble Supreme Court in Government of Andhra Pradesh & Ors. Vs. P.Laxmi Devi, (2008) 4 SCC 720, has observed as under:-

> "46. In our opinion, there is one and only one ground for declaring an Act of the legislature (or a provision in the Act) to be invalid, and that is if it clearly violates some provision of the Constitution in so evident a manner as to leave no manner of doubt. This violation can, of course, be in different ways e.g. if a State Legislature makes a law which only Parliament can make under List I to the Seventh Schedule, in which case it will violate Article 246(1) of the Constitution, or the law violates some specific provision of the Constitution (other than the directive principles). But before declaring the statute to be unconstitutional, the court must be absolutely sure that there can be no manner of doubt that it violates a provision of the

5 Ins. by Act 21 of 1962, sec. 22 (w.e.f. 27-7-1964)
6 Ins. by Act 68 of 1982, sec. 29, (w.e.f. 1-2-1983)
6 Ins. by Act 68 of 1982, sec. 29, (w.e.f. 1-2-1983)

> Constitution. If two views are possible, one making the statute constitutional and the other making it unconstitutional, the former view must always be preferred. Also, the court must make every effort to uphold the constitutional validity of a statute, even if that requires giving a strained construction or narrowing down its scope vide Rt. Rev. Msgr. Mark Netto v. State of Kerala [(1979) 1 SCC 23 : AIR 1979 SC 83] SCC para 6 : AIR para 6. Also, it is none of the concern of the court whether the legislation in its opinion is wise or unwise."

22. As stated in the counter affidavit, the purpose of bringing in the amendments for a joint inspection by Central Drug Inspector and State Drug Inspectors is to ensure uniform quality compliance by the entire pharmaceutical industry. The idea behind the amendment is that an unique inspection procedure is necessary before licence can be granted to ensure that there is no difference in the quality of inspection between one State and another. This being the object of the Act, it cannot be said that the impugned rules introduced through G.S.R 1337(E) dated 27.10.2017 are manifestly arbitrary. There is a nexus between the amendment brought out by the introduction of these rules and the object sought to be achieved by the advent of these rules. There is nothing on record to show that the powers of the State Government have in anyway been denuded or lessened by the introduction of the three rules that have been enforced by G.S.R 1337(E) dated 27.10.2017.

23. It is also contended by the writ petitioner that Section 33 does not give power to make rules for inspection. We are afraid the said argument does not hold water, in view of the Section 33(2)(a) and 33(2)(e) extracted supra. A reading of which would show that the State Government has the power to make rules before granting licence.

24. The learned counsel for the petitioner places heavy reliance on R.M.D.C. (Mysore) Pvt. Ltd., Vs. State of Mysore, (1962) 3 SCR 230. A perusal of the said judgment would show that it deals with the Article 252 of the Constitution of India which is of no relevance or applicability to the present case. Article 252 deals with the power of Parliament to legislate for two or more States for consent and adoption of such legislation by another State. In the present case, as stated above, drugs and poison goods exclusively fall under entry 19 of the Concurrent List. The Parliament is therefore competent to enact any legislation regarding drugs. It will therefore override all legislations enacted by the State Government (if any), that exists prior to the Drugs and Cosmetics Act,1940. In fact, the State Government cannot bring about an Act contrary to the

provisions of Drugs and Cosmetics Act which holds the field unless assent of the President is obtained under Article 254(2). Article 252 therefore has no application in the present case and the reliance placed by the petitioner on the judgment of the Hon'ble Supreme Court in R.M.D.C. (Mysore) Pvt. Ltd., Vs. State of Mysore(supra) is completely misplaced.

25. There is nothing to show that the impugned rules are manifestly arbitrary. The Hon'ble Supreme Court in Shayara Bano Vs. Union of India, (2017) 9 SCC 1, has laid down the parameters as to when a legislation can be termed as "Manifestly Arbitrary". Para 101 of the said judgment reads as under:-

> "101. It will be noticed that a Constitution Bench of this Court in Indian Express Newspapers (Bombay) (P) Ltd. v. Union of India [Indian Express Newspapers (Bombay) (P) Ltd. v. Union of India, (1985) 1 SCC 641 : 1985 SCC (Tax) 121] stated that it was settled law that subordinate legislation can be challenged on any of the grounds available for challenge against plenary legislation. This being the case, there is no rational distinction between the two types of legislation when it comes to this ground of challenge under Article 14. The test of manifest arbitrariness, therefore, as laid down in the aforesaid judgments would apply to invalidate legislation as well as subordinate legislation under Article 14. Manifest arbitrariness, therefore, must be something done by the legislature capriciously, irrationally and/or without adequate determining principle. Also, when something is done which is excessive and disproportionate, such legislation would be manifestly arbitrary. We are, therefore, of the view that arbitrariness in the sense of manifest arbitrariness as pointed out by us above would apply to negate legislation as well under Article 14."

26. The rules under challenge cannot be termed as manifestly arbitrary. Further the fact that the petitioners perceive difficulty in implementing the rule is no ground to strike down the rules as arbitrary and violative of Article 14 of the Constitution of India.

27. In view of the above, the writ petitions are dismissed. No Costs. The oral prayer made for grant of certificate is refused.

s/d-
Assistant Registrar(CS-III)

True Copy

Sub-Assistant Registrar

To

1. Secretary,
   Union of India,
   Health & Family Welfare,
   Nirman Bhavan, New Delhi - 110 011.

2. The Drugs Controller General of India,
   FDA Bhawan, ITO, Kotla Road,
   New Delhi - 110 002.

3. The Secretary,
   State of Tamil Nadu,
   Health & Family Welfare,
   Fort St.George, Chennai - 600 003.

4. The Director fo Drugs Control,
   Office of the Drugs Controller,
   Anna Salai, Teynampet,
   Chennai - 600 018.

5. The Secretary,
   Government of India,
   Ministry of Health and Family Welfare,
   Room No.414-A, D-Wing, Nirman Bhawan,
   New Delhi - 110 011.

+1 CC to Mr.K. Ragu, Advocate sr 17612.
+1 CC to Mr.T.D. Selvam Babu, Advocate sr 17462.
+1 CC to Mr.G. Sankaran, Advocate sr 18535
+1 CC to Mr.G. Karthikeyan, Advocate sr 17901.

W.P.Nos.33924 of 2017 & 4670/2018

PP(CO)
SP(18/05/2020)