

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 17.12.2018

CORAM

THE HONOURABLE Mrs.JUSTICE PUSHPA SATHYANARAYANA

W.P.No.28716 of 2018
and W.M.P.No.33542 of 2018

The Tamil Nadu Chemists and Druggists Association,
Rep by its General Secretary,
Mr.K.K.Selvan,
Having Office at
D-36, 8th Floor,
'D' Block, Halls Towers,
33, Halls Road, Chennai – 600 008 .. Petitioner

Vs.

1. The Union of India,
Through the Department of Health and Family Welfare,
Room No.348, A Wing,
Nirman Bhavan,
New Delhi 110 011.
2. The State of Tamil Nadu,
Rep by its Secretary,
Department of Health and Family Welfare,
Fort St.George,
Chennai.
3. Central Drugs Standard,
Control Organisation,
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India,
FDA Bhavan, ITO, Kotla Road,
New Delhi 110 002.

4. The Drugs Controller,
Drugs Control Department,
359, DMS Compound, Anna Salai,
Teynampet, Chennai 6
5. Netmeds Market Place Ltd,
Rep by Director M/s.M.Pradeep Dadha, Regd,
Office at No.1, Lalithapuram Street,
Royapettah, Chennai -14.
6. Digital Health Platforms,
Rep by President Dharmil Nirupam Sheth,
Registered Office at Flat No.4, Ghatkapar Devang,
CHS Ltd., 90 Feet Road, Garodia Nagar,
Plot No.53, Opp.Savita Park, Ghatkoper(E),
Mumbai – 77.
7. 91 Streets Media Technologies,
Pvt.Ltd.,8/A, Akashdeep, Damodar Park LBS
Marg, Ghatkopar (West), Mumbari – 86
Rep by Director Mr.Dharmil Sheth.
8. Medlife International Pvt.Ltd.,
5th Floor, Tower D, IBC Knowledge Park,
4/1, Banerghatta Main Road, Bangalore,
Karnataka 560 029, Rep by I.Yateesh,
Sr.Executive, Legal and Compliance.
9. M/s.Practo Technologies Pvt.Ltd.,
Rep by its General Manager, RPS Green,
165/5, Krishna Raju Layout, JP Nagar,
4th Phase, Bengaluru 560 076.
10. IMG Technologies Pvt.Ltd.,
Level 3, Vasant Square Mall, Pocket V, Sector B,
Vasant Kunj, New Delhi – 70,
Rep by its Authorised signatory Mr.Jatin Arora
[R5 to R10 are impleaded vide Court order
dated 02.11.2018 made in W.M.P.Nos.34127, 34167,
34182, 34191, 34225, 34274/18 in W.P.No.28716
of 2018 by RMDJ)

11. M/s.TNMEDS,
Rep by its Proprietor,
D.Sridharan,
1/9, Fifth Cross Street,
M.C.Nagar, Chitlapakkam,
Chennai – 64.

12. The Tamil Nadu Marunthalunar Sangam,
Rep by its General Secretary,
Mr.J.Venkatasundaram,
Having Office at D-36, 8th Floor,
D Block, Halls Tower,
No.33, Halls Road, Chennai 600 008,

(R11 and R12 are impleaded vide Court Order
dated 19.11.2018 made in W.M.P.Nos.35355 of 2018
and 35644 of 2018 in W.P.No.28716 of 2016
by PSNJ)

13. Consumer Online Foundation,
Rep through its Managing Trustee,
Having its Registered Office at B-306,
1st Floor, C.R.Park, New Delhi 110 019
R13 impleaded vide Court order dated 05.12.2018
made in W.M.P.No.37043 of 2018 in
W.P.No.28716 of 2018 by PSNJ) ...Respondents.

* * *

Prayer : Writ petition filed under Article 226 of the Constitution of India praying for a Writ of Mandamus directing the respondents to block the link of all such websites, who are carrying on online sale of Schedule H,H1 and Schedule X medicines in violation of Rules 65 and 97 of the Drugs and Cosmetics Rules, 1945, till the licences are granted to sell medicines through online.

* * *

For Petitioner : Mr.G.Masilamani, Senior Counsel
Mr.AR.L.Sundaresan, Senior Counsel
for Ms.A.L.Ganthimathi.

For Respondents : Mr.G.Karthikeyan,
1 to 3 Assistant Solicitor General of India,
Assisted by Mr.N.Ramesh

For Respondents : Mr. S.R.Rajagopal,
2 to 4 Additional Advocate General,
Assisted by Mr.V.Shanmugasundar,
Special Government Pleader

For Respondents : Mr.P.S.Raman, Senior Counsel
5 and 6 for Mr.A.Ramesh Kumar

For Respondent-7: Mr.Sathish Parasaran, Senior Counsel
for Mr.P.Giridharan

For Respondent-8: Mr.P.R.Raman, Senior Counsel
for Mr.Thriyambak J.Kannan

For Respondent-9: Mr.R.Senthilkumar for
M/s.Dua Associates

For Respondent-10: Mr.M.S.Krishnan, Senior Counsel
for Mr.J.R.Jayant
for M/s.Kochhar and Co.

For Respondent-11: Mr.Naveen Kumar Murthy
for Ms.S.Varsha

For Respondent-12 : Mr.G.Vijayakumar

For Respondent-13 : Mr.Amrith Bhargav

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ORDER

What cannot be permitted can be regulated ? This seems to be the Mantra of the Central and State Governments. But the rapid growth of e-commerce continues to present challenges to the State and Central Governments in the trade of on-line pharmacy. The protests made, when Amazon, Flipkart and Snapdeal, entered in

general retail, are being continued in retail medicine. The Central Government continues to lag in passing a specific legislation aimed at the On-line pharmacy industry.

2. The petitioner is an Association of the Tamilnadu Chemists and Druggists, represented by its General Secretary and the Writ Petition has been filed for blocking the link of all such websites from India, who are doing on-line sale of Schedule H, H1 and Schedule X medicines in violation of Rules 65 and 97 of the Drugs and Cosmetics Rules, 1945 (in short "D & C Rules"), till the licenses are granted to sell medicines through on-line.

3. At the outset, there was a preliminary objection raised by the respondents contending that the Writ Petition is barred by the principles of *res judicata*. Earlier, the very same petitioner had filed W.P.No.28325 of 2016 for an identical prayer directing the respondents to block the link of all such websites from India who are selling the on-line medicines. The said Writ Petition was taken up along with another Writ Petition No.5611 of 2016, which was filed for banning of such websites from selling Schedule H medicines in violation of the D and C Rules and the following common order was

passed on 20.12.2016 by a Division Bench of this Court :

"It is stated that the Sub-Committee constituted by the Drugs Consultative Committee (DCC) to examine the issue relating to the sale of drugs over the internet has submitted its report to the DCC, which, in turn, in its 50th meeting held on 4th and 5th November, 2016, has accepted the report and the same has been forwarded to Ministry of Health and Family Welfare for consideration.

2. Learned Assistant Solicitor General states that thereafter it may be put in public domain whereafter final decision will be taken. The process may require about three (3) months.

3. The aforesaid submission is taken on record. No further directions are required in the matter.

4. Writ Petitions are, accordingly, closed. Consequently, W.M.P.No.24439 of 2016 also stands closed.

5. List for compliance on 24.03.2017."

4. The above Writ Petitions were closed on the undertaking given by the Central Government/first respondent therein that the Rules will be published in the public domain within a period of three months. Albeit, only the draft Rules have been published as on date.

5. The contention of the petitioner is that the Central Government has not passed the rules and regulations, but the respondents continue to sell the medicines through on-line. Therefore, permitting sale of drugs through Internet/on-line defeats the purpose of the provisions of the Drugs and Cosmetics Act, 1940 (in short "D &

C Act") and the D & C Rules framed thereunder to safeguard the public interest, which regulates the manufacture and sale to ensure quality and availability under prescribed storage conditions by qualified pharmacists. It is averred in the petition that there are provisions under the D & C Act for recalling drugs due to very serious side-effects from the market and this would be possible only if the medicines are sold by the pharmacists, who are aware of the movement of the medicines till it reaches the patients. There is no guarantee for data privacy if the medicines are sold on-line. Disease and treatment are the private information of the patients, which cannot be made available for data mining and for commercial use by on-line pharmacists.

6. The contention of the private respondents in this regard is that for the very same grounds, the earlier Writ Petitions were filed and disposed of as above and the on-line trading of medicines is continuing. The Division Bench which was conscious of the fact, had only granted time to the first respondent to bring the Rules in a time-bound manner. It is only thereafter, the private respondents would get/obtain licence. It is very specifically argued that the Division Bench of this Court did not ban the continuance of on-line selling of medicines

despite being aware of the prayer made in the Writ Petitions and the fact that the Rules were not in place and the respondents would contend that only if the Rules are notified, there can be compliance of the same.

7. While so, when there is no new cause of action that arose for filing of the present Writ Petition from the date of the disposal of the earlier Writ Petitions till the filing of the present Writ Petition, the present Writ Petition would be barred by principle of *res judicata*.

8. Mr.P.S.Raman, learned Senior counsel appearing for the eighth respondent, placed his reliance on the decision of the Supreme Court reported in ***AIR 1961 SC 1457 (DARYAO AND OTHERS VS STATE OF U.P AND OTHERS)*** to highlight as to whether the rule of *res judicata* is merely a technical rule or it is based on high public policy. Learned Senior Counsel contended that as expressed by the Apex Court in ***(2008) 1 SC 560 [UDYAMI EVAM KHADI GRAMODYOG WELFARE SANSTHA AND ANOTHER -VS- STATE OR UTTAR PRADESH AND OTHERS]***, a writ remedy is an equitable one. A person approaching a superior Court must come with a pair of clean hands and not only should not suppress any material fact, but

also should not take recourse to the legal proceedings over and over again, which amounts to abuse of the process of law. The above said decision was pressed into service to highlight the fact that it has been deliberately stated in paragraph 1 of the affidavit filed by the petitioner that earlier Writ Petition No.28325 of 2016 was filed for the very same relief and the same was said to be pending, when the said petition was dismissed long before the present petition is filed.

9. On the very same issue of *res judicata* and abuse of process of law, Mr.Sathish Parasaran, learned Senior Counsel appearing for the seventh respondent submitted that the law laid down in **1998 (1) CTC 66 [RANIPET MUNICIPALITY, REP BY ITS CORNER AND SPECIAL OFFICER, RANIPET -VS- M.SHAMSHEERKHAN]** would aptly apply to the present case, wherein, the petitioner has resorted to encourage the multiplicity of proceedings amounting to abuse of process of law. It is useful to extract the following passage in paragraph 9 of the said order.

"9. It is this conduct of the respondent that is attacked by the petitioner as abuse of process of Court. What is 'abuse of the process of the Court'? Of course, for the term 'abuse of the process of the Court' the Code of Civil Procedure has not given any definition. A party to a litigation is said to be guilty of abuse of process of the Court any of the following cases:-

- (1) *Gaining an unfair advantage by the use of a rule of procedure.*
- (2) *Contempt of the authority of the Court by a party or stranger.*
- (3) *Fraud or collusion in Court proceedings as between parties.*
- (4) *Retention of a benefit wrongly received.*
- (5) *Resorting to and encouraging multiplicity of proceedings.*
- (6) *Circumventing of the law by indirect means.*
- (7) *Presence of witness during examination of previous witness.*
- (8) *Institution vexatious, obstructive or dilatory actions.*
- (9) *Introduction of Scandalous or objectionable matter in proceedings.*
- (10) *Executing a decree manifestly at variance with its purpose and intent.*
- (11) *Institution of a suit by a puppet plaintiff.*
- (12) *Institution of a suit in the name of the firm by one partner against the majority opinion of other partners etc."*

10. It is pointed out by the learned Senior Counsel that the earlier writ petition, which had verbatim the same prayer, was closed with a direction to the Central Government to formulate the rules in a time-bound manner. However, trading in on-line by the respondents and others was not banned or prohibited till such time.

11. In common law jurisdiction, abuse of process includes want of a valid cause of action, though abuse of process does not require

proof of malice. Abuse of process of law implies malicious and improper use of some regular legal proceedings to obtain some advantage over an opponent. The petitioner, by instituting vexatious and obstructive action in the Court of law, is not only guilty of abuse of multiplicity of proceedings, but also guilty of *suppressio veri* and *suggestio falsi*.

12. Mr.M.S.Krishnan, learned Senior Counsel appearing for the tenth respondent also contended that the act of the petitioner is only a re-litigation, as the present petition is also filed for the same relief without any new cause of action after the final orders are passed in the earlier Writ Petition. Reliance was also placed on the decision reported in **1998 (3) SCC 573 (K.K.Modi Vs. K.N.Modi)**, wherein, the Hon'ble Apex Court held as follows :

"43. The Supreme Court Practice 1995 published by Sweet & Maxwell in paragraph 18/19/33 (page 344) explains the phrase "abuse of the process of the court" thus:

"This term connotes that the process of the court must be used bona fide and properly and must not be abused. The court will prevent improper use of its machinery and will in a proper case, summarily prevent its machinery from being used as a means of vexation and oppression in the process of litigation..... The categories of conduct rendering a

claim frivolous, vexatious or an abuse of process are not closed but depend on all the relevant circumstances. And for this purpose considerations of public policy and the interests of justice may be very material."

44. *One of the examples cited as an abuse of the process of court is re-litigation. It is an abuse of the process of the court and contrary to justice and public policy for a party to re-litigate the same issue which has already been tried and decided earlier against him. The re-agitation may or may not be barred as res judicata. But if the same issue is sought to be re-agitated, it also amounts to an abuse of the process of court. A proceeding being filed for a collateral purpose, or a spurious claim being made in litigation may also in a given set of facts amount to an abuse of the process of the court. Frivolous or vexatious proceedings may also amount to an abuse of the process of court especially where the proceedings are absolutely groundless. The court then has the power to stop such proceedings summarily and prevent the time of the public and the court from being wasted. Undoubtedly, it is a matter of the courts' discretion whether such proceedings should be stopped or not; and this discretion has to be exercised with circumspection. It is a jurisdiction which should be sparingly exercised, and exercised only in special cases. The court should also be satisfied that there is no chance of the suit succeeding.*

....

46. *In Mcllkenny v. Chief Constable of West Midlands Police Force and another [1980 (2) All ER 227], the Court of Appeal in England struck out the pleading on the ground that the action was an abuse of the process of the court since it raised an issue identical to that which had been finally determined at the plaintiffs' earlier criminal trial. The court said even when it is not possible to strike out the plaint on the ground of issue estoppel, the action can be struck out as an abuse of the process of the court because it is an abuse for a party to re-litigate a question or issue which has already been decided against him even though the other party cannot satisfy the strict rule of res judicata or the requirement of issue estoppel."*

13. Refuting the allegation of abuse of process of law and the writ petition is hit by the principle of *res judicata*, Mr.AR.L.Sundaresan, learned Senior Counsel appearing on behalf of the petitioner submitted that though the respondents claimed that the earlier writ petition was disposed of, it was directed to be listed 'for reporting compliance' and hence, the petitioner was under the impression that it was kept pending and on that score it cannot be stated that there is a suppression of fact and the act of the petitioner is abuse of process of law. It is the claim of the learned Senior Counsel for the petitioner that the act of filing the counter affidavit by the first respondent during the

month of February, 2017, in the said writ petition, which was allegedly disposed of by then, would go to show that even the first respondent/Union of India was placed with such impression. There is no *res judicata*, much less constructive *res judicata*, as there is no adjudication and order of the Court finalizing the issue raised before it. Hence, it cannot be stated that the persons have been vexed twice.

14. The Court will normally use *res judicata* to deny reconsideration of a matter. The doctrine of *res judicata* is only a method to prevent injustice to the parties of a case supposedly finished. In the given case, all the private respondents were not parties to the previous case. The said writ petition was also not decided on merits. Therefore, the issue of law was not decided and also not between the same parties. Hence, there is no *res judicata*.

15. As the Internet evolved and pervaded into the Country, the retail market had adopted a new technology adding one more medium to reach the consumers. When offering products including food items and other consumables are accepted, the trading of on-line medicine alone is challenged now. With lower price and easy accessibility, the members of the petitioner-Association feel hurt and threatened. The

on-line prices are certainly 10-20% lower than the purchasing price from brick and mortar stores. The reasons are the on-line vendors cut so many of the overheads like real estate, inventory, salary to employees, agencies etc. However, the only challenge faced by them is the timely delivery of the same to the right persons. In on-line trading of medicine, the requirement imposed on a customer is the prescription of a drug, but it is alleged by the petitioner that on-line pharmacists do not comply with the laws and are selling prescription drugs and controlled substances without valid prescription and they are also offering discounts for bulk purchases of prescription drugs, but on the other hand, there are several benefits to a purchaser of on-line.

16. It is uniformly contended by the learned Senior Counsel appearing for the respondents that purchasing the medicines through on-line is physically easier than going to the pharmacies. For the senior citizens, i.e., the age group that spends most on drugs, the consideration is an important one. The on-line medium offers modern medical care tools and as such, their reminder information about the medicines and also render round the clock assistance. On-line pharmacies allowed the patients to purchase the drugs discreetly without face to face interactions. The rise in on-line pharmacies also

creates more supply options for the purchasers to find the best service and price. The above benefits undoubtedly have contributed to the growth of the on-line trading, of-course, without licence. On-line vending provides convenience. For the elderly and those who have mobility issues, the on-line delivery medium is crucial.

17. While considering the benefits and advantages in the on-line trading, there are also several risks which are unique to the on-line trading. A patient receives a prescription drug based on on-line questionnaire instead of a valid prescription, which may result in serious side effects and this may be the most common risk without any regulation. The on-line selling of medicines does not require valid prescription, even when selling the prescription drugs. Secondly, the chance of the prescription drugs are delivered without any information to the patients. Yet another risk is that the patient may receive the counterfeit drugs, which are sub-standard or super-potent or adulterated. Counterfeit drugs are manufactured in packages and distributed without regulatory oversight and control exercised over genuine drugs. The important and major risk of purchasing drugs from an on-line store is the misuse of medical, financial and electronic information of patients. Even if the regulations, which are at draft

stage in place, the sale of medicines through Internet intermediaries and the State and Central Governments cannot control the illegal sales, perhaps, the co-ordination of efforts may prove effective. The internet search engines are the most commonly used intermediaries on-line. The search engines like Google exercise little control over their contents.

18. In the counter affidavit filed by the fifth respondent, it is stated that they are not violating any law and they are meticulously following the mandatory provisions, i.e., Sections and Rules. It is specifically stated in the counter affidavit that they ensure compliance of Rules 65(4) (1), 65 (4)(3), 65(4)(4), 65(5)(1), 65(5)(3), 65(9)(a) and 65(9)(b) of the D and C Rules. It is also stated that as per Rule 65, Clause 11 of the D and C Rules, the person dispensing a prescription, containing a drug specified in Schedule H, shall comply with the requirements in addition to the other requirements of these D & C Rules viz., the prescription must not be dispensed for more than once, unless the prescriber has stated thereon that it may be dispensed more than once.

19. Similarly, the seventh respondent has stated in the counter affidavit that it is only a platform connecting the users/customers who intend to purchase medicines with the pharmacies. The seventh respondent itself does not engage in manufacture or sale or distribution or stock or exhibit or offer for sale, or distribute any pharmaceutical drugs. On the contrary, the seventh respondent merely provides only logistic services acting as an agent of the customers and the sale of medicines and it is not involved in the manufacture or sale or distribution, or stocking or exhibiting or offering for sale, or distributing any pharmaceutical drugs. Hence, the seventh respondent is not required to obtain any license under the D & C Act and the Rules framed thereunder. Licenses are obtained by the pharmacists, who are empanelled with the seventh respondent.

20. The ninth respondent, M/s.Practo Technologies Private limited on whose behalf learned counsel Mr.Senthil Kumar appeared and submitted that it does not operate or control, hospitals, clinics, pharmacies or pharmacists, but merely provides information on the above. As on date, about 250 licensed pharmacies are registered on the ninth respondent's website and the ninth respondent has not permitted to register on its platform to sell the prescription medicines

without a valid licence under the D & C Act. The business model of the ninth respondent is only to facilitate the sale and purchase of medicines on its website. Any patient intending to purchase prescription drugs is required to upload a valid prescription for such purchase from a licensed medical practitioner. It is stated that the system itself is designed in such a manner that a request for prescription drugs would be rejected, unless a valid prescription is uploaded with such request. The request for prescription drugs (i.e) accompanied by a valid prescription, is acted upon by the licenced pharmacy (i.e) situated in or adjacent to the locality where the patient resides. The said licenced pharmacy thereafter is required to verify the prescription and if the same is in order, dispense the medicines from the licensed premises to the patient. Thus, the ninth respondent claims that it is also only facilitating the patients' transactions of sale and purchase of medicines and the system generates a verifiable audit trail in respect of the entire process. As the ninth respondent claims that it is not indulging in the on-line medicines, it is submitted that the on-line sales are facilitated from a licenced pharmacy, which is not in violation of Rules 61 and 65 of the D and C Rules.

21. Learned counsel appearing for the tenth respondent submitted that the petitioner had approached this Court with unclean hands. The tenth respondent's contentions are also similar to the ninth respondent and they do not engage in any of the specified activities. It only provides a technology platform to connect the consumers to the brick and mortar third party licenced pharmacies and the sale of medicines itself is concluded directly between the third party licenced pharmacies and the customers. The medicines are always dispensed by the third party licenced pharmacies against the prescription in compliance with all the provisions of the said Act and the Rules. The tenth respondent only connects consumers to the brick and mortar pharmacies and there is no provision under the said Act and the Rules prohibiting the working of such technology platforms. The tenth respondent also stated that the public interest is served by operation of the technology platforms, since they empower consumers having access to "hard to find" medicines, more so, with rare disease and convenience of medication ordered specially for sick, elderly working professional and for patients with disability.

22. Pharmacies and Druggists have long sought to shield their market from on-line traders of medicines protecting consumers in the

process. There is no distinction between legitimate and illegitimate on-line medical store. Intermediaries, who profit from dealing with on-line pharmacies, have no regulations. It is their broad reach and function, they are able to balance their interests. Another crucial lifelines in Internet commerce is the financial intermediary. They impose their own condition of use. Again, here only a handful of companies dominate the majority of the market.

23. The growth of on-line purchase of medicines is encouraged also by the direct exposure to pharmaceutical advertisement. The increased exposure to pharmaceutical products through all modes of communication like Television, Radio, Internet, etc. coupled with less face to face consultation has given patients a false sense of empowerment. The practice of "self-diagnose" by consumers also drive them to on-line pharmacies. On-line pharmacies provide consumers the ability to compare the price and availability also. While it is time-efficient, it affords more privacy than the brick and mortar pharmacy.

24. In fact, in the counter-affidavit of the Union of India, the recommendations, after the deliberations in the 47th Meeting of Drugs

Consultative Committee (in short "DCC"), are extracted which says that "the issue has become international and is being investigated by the international regulatory and law enforcement agencies as well as Interpol. The State Drug Controllers were asked to maintain a vigil in their States to ensure that such activities are not permitted in their States in the interest of the human health. It was however, felt that import of small quantities of medicines by the genuine importers for their personal use complying with the requirements of sale under the Drugs and Cosmetics Rules, 1945 should not be stopped." Further, it is stated that it would be difficult to deny the advent of new technologies leading to the development of E-commerce. It was further recommended that there has to be an open-minded approach to the matter.

25. In the 50th Meeting of the DCC, the report of the Subcommittee qua the examination of the regulations for sale of drugs over Internet and recommended to the Central Government for consideration and further action. Hence, public notice dated 16.03.2011 was issued inviting comments from various stakeholders. The Union of India also seems to have received numerous comments and suggestions from various stakeholders, including the All India

Chemists and Druggists Association, wherein, the petitioner association is a member, and the Indian Internet Pharmacies Association. After deliberations on the concerns raised by the stakeholders, the Central Government decided to bring a regulatory framework for the sale of on-line medicines.

26. Thus, the notification in G.S.R.817(E), dated 28.08.2018 was issued by the Department of healthy and Family Welfare, Ministry of Health and Family Welfare, Government of India, publishing the draft rules to amend the D & C Rules, once again calling for objections and suggestions from all the stakeholders to be considered by the Central Government. The comments and suggestions were received and after due deliberations, the draft rules have to be published for finalization in the official Gazette. Therefore, as on date, there are no proper rules or regulations for on-line trading of medicines.

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27. The State Government has conveniently shirked the responsibility stating that as the D & C Act is a central legislation, any addition/deletion/amendment under the provisions of the D & C Act, can be done only by the Central Government.

28. At this juncture, it is to be stated that Section 18 of the D & C Act, prohibits manufacture and sale of certain drugs and cosmetics and Clause (c) of Section 18 reads as follows :

"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 -

.....

(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 license issued for such purpose under this Chapter."

29. According to the learned Senior Counsels for the petitioner, Rule 61 of the D & C Rules provides for various forms of licenses, i.e., Forms 20, 20-A, 20-B, 20-F, 20-G, 21-A and 21-B, to be obtained for selling and distributing drugs. Relying upon Rule 62 of the D & C Rules, it is contended that if drugs are sold or stored for sale at more than one place, separate application shall be made and a separate license shall be obtained in respect of each such place. Rule 65 of the D & C Rules provides the conditions of licenses stating as to how sale and supply should be made in accordance with the license conditions and only in the presence of a registered Pharmacist.

30. Chapter III of the D & C Act deals with import of drugs and cosmetics, while Chapter IV takes care of manufacture, sale and distribution of drugs and cosmetics. Sections 12 and 33 of the said Act fall under the above Chapters respectively empower the Central Government to make rules concerning the said aspects. In exercise of such power, the present notification was issued.

31. Rule 67-I of the proposed rules contains definition clauses defining 'e-pharmacy', 'e-pharmacy portal', 'Central Licensing Authority', 'prescription' and 'sale by way of e-pharmacy'. Rule 67-J mandates the registration of e-pharmacy, while Rules 67-L and 67-M specify the application for registration and conditions of registration respectively. According to Rule 67-Q, the registration issued to any person shall remain valid for a period of three years, which can be renewed under Rule 67-R. Rule 67-N provides for granting registration. Rule 67-K speaks about the disclosure of information generated through e-pharmacy portal. Rule 67-O empowers the Central Licensing Authority to depute officers for periodic inspection. Rule 67-P lays down procedure for distribution or sale of drugs through e-Pharmacy. Prohibition of advertisement of drugs is imposed under Rule 67-S. Rule 67-T empowers the Central Licensing Authority to suspend or

cancel the registration with provisions to appeal and deemed cancellation. Rule 67-U and 67-V deal with complaint redressal mechanism and monitoring of e-Pharmacies. These provisions are intended to regulate the on-line trade of drugs and cosmetics and to prevent abuse of drugs.

32. Countries like U.S.A. which has the new laws in place also finds the enforcement of the same as a difficult challenge. While the pros and cons of the on-line pharmacy is debated, the stakeholders and the Central and State Governments are aware of the need for a cohesive system of regulation to be notified regulating on-line drugs trade.

33. Mr.P.S.Raman, learned Senior Counsel appearing for the eighth respondent had placed his reliance in this regard on **Suresh Jindal V. Bses Rajdhani Power Ltd., (2008) 1 SCC 341**, wherein, it is held as follows :

"45. Section 20 operates in one field, namely, conferring a power of entry on the licensee. The said provision empowers the licensee inter alia to alter a meter which would include replacement of a meter. It is an independent general provision. In absence of any statutory provision, we do not see any reason to put a restrictive

meaning thereto. Even under the [General Clauses Act](#), a statutory authority while exercising statutory power may do all things which are necessary for giving effect thereto. There does not exist any provision in any of the statutes referred to hereinbefore which precludes or prohibits the licensee to replace one set of meter by another. If such a provision is read into the statute, the same would come in the way of giving effect to the benefits of new technological development. Creative interpretation of the provisions of the statute demands that with the advance in science and technology, the Court should read the provisions of a statute in such a manner so as to give effect thereto. (See **State of Maharashtra V. Dr.Praful B.Desai, [2003] 3 SCC 601**).

34. In this case also, though there is a statute, the regulatory rules are yet to be notified, in the wake of advancement of technology. Unless the legislation keeps pace with the technology, the commerce based on technology has to lag behind.

35. While the draft rules are published in the Gazette, they are yet to be notified. Once it is notified, there is bound to be disagreement between law makers, drug companies, on-line traders and finally the consumers. In the absence of any Central or State Government legislation or rules, on-line sale of prescription drugs could hardly be curbed.

36. The Central Government had already been given a longer rope by the order of the Division Bench, which was passed as early as on 20.12.2016. Though around two years have passed from the date of the said judgment, the rules are still at the draft stage.

37. For the reasons set hitherto, it becomes necessary for the Central Government to notify the rules at the earliest in the interest of public and the on-line drug trade. Accordingly, respondents 1 and 3 are directed to notify the proposed Drugs and Cosmetics Amendment Rules, 2018 in the Gazette at the earliest, however, not later than 31.01.2019. Thereafter, the concerned stakeholders, namely, persons doing trade in on-line pharmacy have to obtain their licences in the manner prescribed in the rules to be notified, within a period of two months from the date of such notification.

38. As the draft rules are framed by the Central Government, after deliberations including the stakeholders, till the aforesaid rules are notified, the on-line traders are bound not to proceed with their on-line business in drugs and cosmetics.

39. With the above directions, this writ petition stands disposed of. However, there shall be no order as to costs. Consequently, connected miscellaneous petition is closed.

17.12.2018

Speaking / Non-speaking Order

Index : Yes/No

Internet : Yes

gg/srn

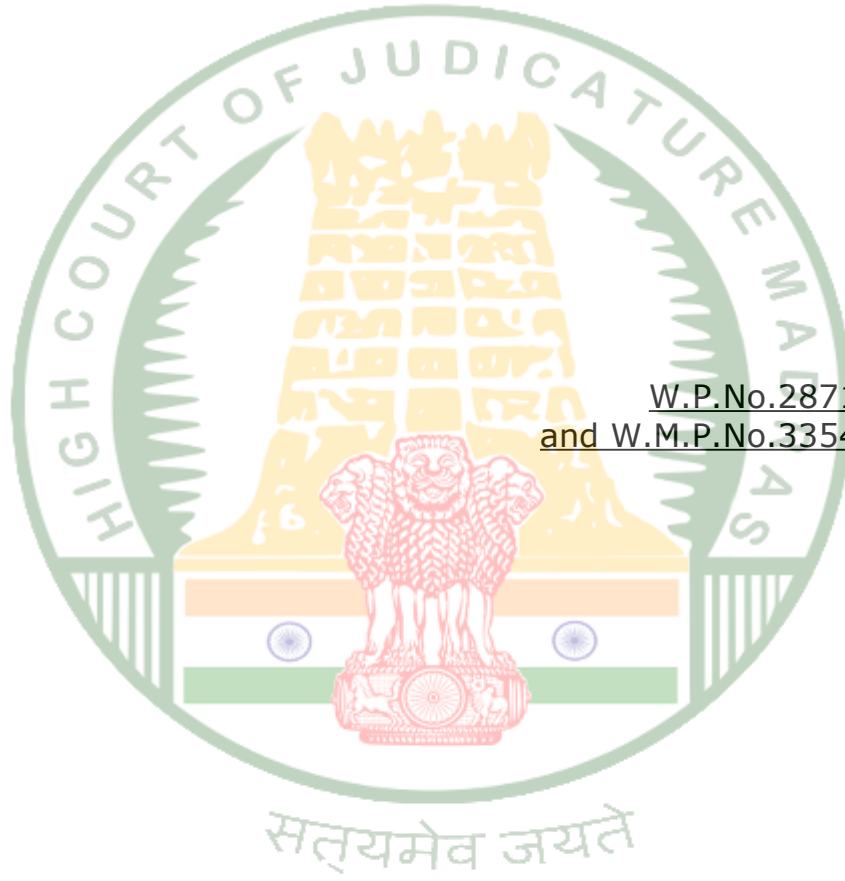
To

1. The Union of India,
Department of Health and Family Welfare,
Room No.348, A Wing,
Nirman Bhavan,
New Delhi 110 011.
2. The Secretary,
Department of Health and Family Welfare,
State of Tamil Nadu,
Fort St. George,
Chennai.
3. Central Drugs Standard Control Organization,
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India,
FDA Bhavan, ITO, Kotla Road,
New Delhi 110 002.
4. The Drugs Controller,
Drugs Control Department,
359, DMS Compound, Anna Salai,
Teynampet, Chennai - 600 006.

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PUSHPA SATHYANARAYANA, J.

srn



W.P.No.28716 of 2018
and W.M.P.No.33542 of 2018

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17.12.2018

W.P.No.28716 of 2018

PUSHPA SATHYANARAYANA, J.

After the pronouncement of the order, learned Senior Counsels appearing for the private respondents submitted that the on-line drug traders will be forced to unplug the trade of on-line medicines till they prefer an appeal and requested not to give effect to the order.

2. Heard the learned Senior Counsel appearing on behalf of the petitioner.

3. Having regard to the submissions of either side, the order passed today will not be given effect to till 10.30 a.m. on 20.12.2018.

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17.12.2018

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