Cipla Limited, Mumbai and Another Vs Union of India (UOI) and Others

Writ Petition No"s. 3031, 3449 and 5219 of 1996, 1749 of 1999 and 1758, 1974, 2019, 2051 and 2060 of 2000 and Contempt Petition No. 96 of 2000

Court: Bombay High Court

Date of Decision: Aug. 31, 2001

Acts Referred:
Constitution of India, 1950 â€" Article 14#Essential Commodities Act, 1955 â€" Section 3

Citation: (2002) 1 ALLMR 75 : (2002) 1 BOMLR 62 : (2002) 2 MhLj 631

Hon'ble Judges: B.P. Singh, C.J; S. Radhakrishnan, J

Bench: Division Bench

Advocate: K.S. Cooper, S.K. Cooper, P.M. Palshikar, I.M. Chagla, D.J. Khambata and Vivek Menon, instructed by Federal and Rashmikant, R.A. Kapadia and N.H. Seervai, instructed by Dhru and Co, for the Appellant; Harish Salve, Solicitor General of India, H.V. Mehta, M.M. Sakhardande and R.V. Desai, for the Respondent

Judgement

S. Radhakrishnan, J.
All the above petitions raise certain common issues of law and involve similar facts, hence we are disposing of the

same by this common judgment.

2. In Writ Petition No. 1749 of 1999 Cipla Limited and Anr. v. Union of India, and Ors. the brief facts and submissions are as under :--

3. The First Petitioner Company is a domestic pharmaceutical company which manufactures and sells various pharmaceutical bulk drugs and

formulations. The present petition is filed challenging :--

(a) The totally arbitrary, unjustified and mala fide refusal by the Respondents to issue the exemption notification to the petitioners to which they are

entitled, and which has already been directed to be issued exempting Salbutamol and its formulations manufactured by the first Petitioners from the

ambit of price control in view of the new process developed by the petitioners by virtue of its indigenous R & D, and in view of Drugs (Price

Control) Order of 1987 providing for such an exemption, under Clause 28 thereof,

(b) The wrongful, illegal and arbitrary inclusion of the drugs Salbutamol and Theophyline within the ambit of price control despite the fact that the

new drug policy 1994 of the Respondents provides specific parameters for the inclusion of drugs within the ambit of price control and the aforesaid

formulations of the petitioners do not fall within the scope of the said drug policy.

(c) Totally in a discriminatory and arbitrary manner the Respondents have fixed the price for the formulations of Salbutamol sold by the petitioners

without fixing any price for similar products generally, thus singling out the petitioners for coercive action.

4. It is the case of the petitioners that they manufacture Salbutamol which is a bronchodilator for the treatment of asthma and also they manufacture

formulations of Salbutamol along with Theophyline. These products which are used for the treatment of Asthma are sold at prices ranging from 30

paise to 90 paise per dose which prices are amongst the cheapest in the world. It is the contention of the petitioners that the first petitioner

company has begun manufacturing Salbutamol since 1976, and the said Salbutamol is not a Scheduled drug, and that the price of the drug has

remained unchanged since 1976. The major formulation which was sold by the petitioners with regard to the said drug is sold in a strip of 10

tablets costing barely Rs. 3.43 ps. It appears that for the first time, the Drugs Price Control Order of 1979 classified the aforesaid Salbutamol as a

bulk drug and no sale price was fixed. In September, 1988 the first petitioner company M/s Cipla Limited had developed a new and innovative

process for the manufacture of Salbutamol and had commenced the commercial production and by this time sale price was also fixed for

Salbutamol. Thereafter, it appears that on 10th October, 1990 the Respondents herein had issued a notification exempting M/s Cipla Ltd. from

price control in respect of Salbutamol and its formulations for a period of 5 years from September, 1988 to 31st August, 1993. It is the contention

of the petitioners that in 1993, M/s Cipla Limited had developed through its own indigenous R & D, a newer, more efficient and more cost

effective process for the manufacture of Salbutamol. On 25th August, 1993 M/s Cipla Ltd. had applied to the first Respondent Union of India for

exemption of Salbutamol from the provisions of the DPCO on the ground of R & D based on its new process. On 10th December, 1993 Union of

India had acknowledged the receipt of aforesaid application but had asked for a new proforma from M/s Cipla Limited.

5. On 25th October, 1994 Union of India had formulated a new drug policy known as the New Drug Policy, 1994 which contained the guidelines

for the first time setting out the criteria by which the drugs should or should not be included under the price control, and the petitioners had been

representing to the Respondents for the exclusion of Salbutamol from the ambit of price control under the new policy. Broadly the said policy had

prescribed that any drug with an annual turnover of below Rs. 400 lacs should be excluded.

6. Meanwhile on 10th December, 1996 this Court by an interim order in Writ Petition No. 569/1996 had held that the value of exports will have

to be excluded while determining minimum annual turnover, and that the minimum annual turnover of Rs. 400 lacs must be determined on the basis

of annual sales figures as per ORG, and that the minimum annual turnover must not be determined on the basis of any hypothetical calculation

based on cost of production etc. And after laying down the principles for determining inclusion and exclusion, this Court granted interim relief to the

manufacturer of drugs whose products had been wrongfully included in the ambit of price control. It appears that the ORG Data for the relevant

period prescribed under the Drug policy (i.e.89-90) for the said drug Salbutamol shows a turnover of Rs. 171.03 lakhs. The Drug Policy had also

prescribed that if there were to be at least 5 bulk drug producers and at least 10 formulators and none have more than 40% market share the drug

should be excluded from price control. The policy had also required that the market share should be determined with reference to ORG figures. It

appears that as per the ORG figures for the relevant period, there were at least 5 bulk drug producers and at least 10 formulators for Salbutamol

and ORG had themselves certified that no one had more than 40% market share. Similarly, it appears that, for Theophyline, there were at least 5

bulk drug producers and at least 10 formulators and none of whom had more than 40% market share as per ORG. The petitioners had specifically

furnished the names and addresses of each of the said bulk drug producers and formulators.

7. In December, 1997, one Writ Petition bearing No. 5578/1997 was filed in the Delhi High Court by the Bulk Drug Manufacturers Association of

which the first petitioner M/s Cipla Limited was a member. The said petition interfacial had challenged the wrongful inclusion of several drugs within

the ambit of price control, two of these drugs being Salbutamol and Theophyline. On 10th June, 1997 one circular letter had been issued by the

Respondents directly contrary to the orders of the Bombay High Court as aforementioned. In the said letter it was mentioned that the exports

would be included in determining the turnover and that the ORG figures will not be considered. The aforesaid petition being Writ Petition No.

5578/1997 has been admitted by the Delhi High Court and is pending for final hearing. It appears that by an interim order passed in the aforesaid

Writ Petition on 7th January, 1999, the Delhi High Court had directed that no action should be taken against the manufacturers of 8 drugs on the

basis of their inclusion within the price control. These 8 drugs include Salbutamol and Tehophyline. It further appears that by an affidavit dated 2nd

February, 1999 filed in the Delhi High Court in the aforementioned proceedings, the third Respondents have attempted to work out the turnover of

Salbutamol based upon the alleged cost of production ignoring actual sales figures as per ORG.

8. It appears that for the first time in the year 1979 the said drug Salbutamol has been brought within the ambit of price control, and there was no

price fixation for Salbutamol based formulations until 1987. It appears that M/s Cipla Limited which manufacturers around 20 different

formulations based on Salbutamol of which 18 formulations have a price fixed for them.

9. In Writ Petition No. 3449 of 1996 Raj Medicals and Ors. v. Union of India, and Ors. the learned Counsel Mr. Iqbal Chagla has submitted that

the petitioner No. 2 ""Ranbaxy"" has from about May, 1989 had manufactured the bulk drug ""Ciprofloxacin"" which is captively consumed by

Ranbaxy in the manufacture of formulations marketed under the bandanna ""Cifran"" from about 10th June, 1989. In this petition, the petitioners

have challenged the inclusion of Ciprofloxacin (as Item 27) in the First Schedule to the Drugs Price Control Order, 1995 (""DPCO 1995"") and the

subjecting of Ciprofloxacin to price control. The petitioners have also challenged the consequential issue of the notification dated 3rd April, 1996

fixing the maximum price of Ciprofloxacin under the DPCO 1995. It is an admitted position that prior to the introduction of the DPCO 1995

neither the said bulk drug Ciprofloxacin nor the formulations made therefrom were brought under price control.

10. The DPCO 1995 has been issued in exercise of powers u/s 3 of the Essential Commodities Act, 1995 and pursuant to the New Drug Policy

1994 issued on 15th September, 1954 by the Ministry of Chemicals and Fertilizers, Government of India. Previously, the following drugs price

control orders had been issued :--

A. The Drug Price Control Order, 1970.

B. The DPCO 1979 published on 3Ist March, 1979 had repealed the earlier DPCO 1970 and DPCO 1979 was issued pursuant to the statement

on Drug Policy 1978. The Drugs Policy 1978 was formulated based on the report of the Committee on Drugs and Pharmaceutical Industry made

in April, 1975 (the Hathi Committee Report),

C. The DPCO 1987 published on 26th August, 1987 repealed the earlier DPCO 1979. The DPCO 1987 was issued pursuant to the Drug Policy

1986 ""Measures for Rationalization, Quality Control and Growth of Pharmaceutical Industry 1986-1987."" Again DPCO 1987 was repealed by

the DPCO 1995.

11. Mr. Chagla, the learned Counsel has submitted that as far as the Drugs Policy 1986 was concerned, it recognized the considerable change in

the pharmaceutical sector since the Drug Policy 1978 and had sought to give ""new thrust and direction"" to subserve the objective of growth of the

Pharmaceutical Industry. The objective of the Drugs Policy 1986 was to ensure abundant availability at reasonable prices all essential life saying

and prophylatic medicines of good quality, to strengthen the system of quality control over drug production and promote the rational use of drugs in

the country, to create an environment conducive to channelising new investment into the pharmaceutical industry, to encourage cost-effective

production with economic sizes and to introduce new technologies and new drugs and to strengthen the indigenous capability for production of

drugs. It appears that both the DPCO 1979 as well as the DPCO 1987 contained the same provisions in para 3(1) thereof which reads as under:-

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3. Power to fix the sale price of indigenously manufactured bulk drugs specified in the first or second schedule. -- (1) The Government with a

view to regulate the equitable distribution and increasing supply of an indigenously manufactured bulk drug specified in the First or Second

Schedule and making it available from different manufacturers at fair prices, after making such inquiry as it deems fit, fix from time to time by

notification in the Official Gazette, a maximum sale price at which such a bulk drug shall be sold;

Provided that for the purpose of enquiry, details in Form-1 of Fourth Schedule and such additional details as may as required shall be provided by

the manufacturers twice a year viz. 31st January and 30th June, in a year or as and when required by the Government:

Provided further, that where the Government fixes more than one price for a bulk drug produced by different manufacturers, on account of

different options exercised by manufacturers of such bulk drug under sub-paragraph (2), Government may also fix a weighted average price for

such bulk drug which shall be considered in fixation of prices of formulations containing such bulk drug.

12. The Respondents had established a Committee known as ""Kelkar Committee"" consisting of representatives of the Department of Chemicals

and Fertilizers the Ministry of Health and the Bureau of Industrial Costs and Pricing as well as of the State Governments. The Committee was

chaired by the then Chairman of BICP Mr. Kelkar and was popularly known as the Kelkar Committee. It was constituted to draw up the lists of

drugs to be included in Category I and Category II of the DPCO 1987 and adopted five criteria for inclusion/exclusion of drugs in Category II i.e.

drugs other than those in Category I but which were also considered essential for health needs and would carry MAPE of 100%. It appears that in

or about 1987 the Kelkar Committee was further directed to review the aforesaid list and to consider the several representations made against

inclusion in the said lists which were contrary to the aforesaid five criteria. Upon such a review, the Kelkar Committee had recommended the

exclusion of 47 drugs from Category II out of the total of 139 recommended for price control by the Kelkar Committee itself. The Kelkar

Committee had also recommended the inclusion of 4 bulk drugs in the said list since they fulfilled the aforesaid inclusion criteria. It further appears

that on or about 27th February, 1990 the first Respondent - Union of India had also included 21 further drugs under the price control. However,

notably the Ciprofloxacin was not included under the price control despite the aforesaid inclusions, as pointed out by Mr. Chagla.

13. Mr. Chagla then submitted that as far as new Drugs Policy 1994 was concerned, it acknowledged arbitrariness and lack of transparency in the

inclusion/exclusion of bulk drugs under price control. In this context paragraphs 9 and 10 thereof are relevant. In paragraph 22.7.2 under the

heading of ""Span of Control"" certain established criteria/guidelines were set out. Paragraph 22.7.4 thereof provided for a simplified procedure. The

said Drugs Policy 1994 recognised the vastly improved export performance of the Pharmaceutical Industry and noted that the industry had been a

net exporter during the last four years as well as that the Pharmaceutical Sector had been identified as one of the thrust areas for exports.

14. So far as the DPCO 1995 was concerned, in keeping with the focus of the Drugs Policy 1994 viz. the special emphasis on turnover as an

index of the extent of usage of a drug and on ensuring the equitable distribution and abundant availability of drugs of good quality as well as to

introduce new technologies and new drugs in India, Para 3(1) of the DPCO 1995 came to be modified. It was submitted that the criteria for

inclusion in the First Schedule of the DPCO 1995 which were mandatorily required to be observed, were set out in para 22.7.2 of the Drugs

Policy 1994, and the said criteria was to operate as under:--

(i) a minimum annual turnover of Rs. 400 lakhs considered a sufficiently high turnover as an index of extent of usage and therefore to be included

under price control:

Provided however where even though the turnover exceeds Rs. 400 lakhs but there is sufficient market competition, i.e. at least 5 bulk drugs

producers and at least 10 formulators, none having more than 40% market share in the retail trade (as per ORG) the drug is excluded from price

control.

(ii) Even where the annual turnover is less than Rs. 400 lakhs but where it is greater than Rs. 100 lakhs then if the drug is of popular use in which

there is a monopoly situation, i.e. if there is a single formulator having 90% or more market share in the retail trade (as per ORG) the drug is to be

included under price control.

15. It appears that as per ORG Data for the year ending in 31st March, 1990 as per the provisions of para 22.7.2(v), the domestic sales turnover

of the formulation from the bulk drug Ciproflozacin was Rs. 867 lakhs. Working backwards, the aggregate turnover of the bulk drug Ciprofloxacin

was Rs. 288 lakhs and there were several formulators of formulations from Ciprofloxacin and there was no single formulator having 90% or more

market share in the retail trade.

16. Mr. Chagla, the learned counsel submitted that the reference to ""Annual turnover"" in para 2.7.2. (i) is a reference to domestic sales turnover of

the bulk drug that is to say the aggregate quantity of the bulk drugs sold in the domestic market (whether, produced in India or imported from

abroad) and cannot include the quantity of the bulk drugs imported or produced in India but exported. It is further submitted that the DPCOs only

exercise power u/s 3 of the Essential Commodities Act, 1955 and cannot purport to nor are they intended to regulate prices of essential

commodities, i.e. drugs outside the territorial limits of India, Section 3(1) of the Act, provides as under :--

3. Powers to control production, supply, distribution, etc. of essential commodities. -- (1) If the Central Government is of the opinion that it is

necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and

availability at fair prices (or for securing any essential commodity for the defence of India or the efficient conduct of military operations), it may, by

order, provide for regulating or prohibiting the production, supply and distribution thereof and trade and commerce therein.

. 17. It is further submitted by the petitioners that the object and purpose of the Drugs Policy 1994 and the DPCO 1995 was to ensure cheap and

ready availability of drugs in India by the use of transparent and objective criteria. As stated in para 9 of the Policy the high turnover of a drug is an

index of its extent of usage and is considered to meet the requirement of objectivity justifiable on economic considerations. The object was not to

restrict foreign exchange earnings of Indian Drug Companies whereby our Country was also benefitting. The intent and purpose of the word

turnover"" as used in para 9 of the Drugs Policy 1994 i.e. ""to determine the extent of the usage of a bulk drug in the country"" has been emphasized

in the Affidavit in Reply in para 3(v) at page 155. It is submitted that this would mean that the emphasis is on determining the usage of the bulk drug

in the country that is to say the sales turnover, and in other words exports must necessarily be excluded. It appears that the expression ""turnover

and ""sales turnover"" are used interchangeably in the Drug Policy 1994 and the DPCO 1995. It is further borne out by the fact that under para

20(1) of the DPCO 1995 every manufacturer and importer is required to maintain records relating to the ""sales turnover of individual bulk drugs

manufactured or imported by him as the case may be, and the sales turnover of formulations pack-wise at the premises of the manufacturer or

importer and also such other records as may be directed from time to time by the Government and the Government shall have the power to call for

such records or to inspect such records"". Para 20(2) also requires such manufacturer or importer to submit to the Government within six months of

the close of the accounting year information in respect of ""turnover and allocation of sales and expenses for that year....."". Para 20(3) requires

every dealer, manufacturer or importer to maintain the cash memo or credit memo, books of account and records of purchase and sale of

drugs....."". So far as para 25 of the DPCO 1995 is concerned it lays down the factors that are to be taken into account whilst granting exemption

to any manufacturer from the operation of all or any of the provisions of the DPCO 1995. One of the factors is ""sales turnover"" to be taken into

account whilst granting exemption. It is also submitted by the petitioners that it would be arbitrary and perverse to utilise ""production and imports

for deciding inclusion whilst only ""sales turnover"" granting exemption. It appears that the Respondents in their affidavit in reply contend that whilst

one standard is to be adopted for the term ""turnover"" in para 22.7.2 (i) (viz. the value of the total production of the bulk drugs in the country and

the value of weighted landed cost of its total import into the country), a different standard is to be applied for the criteria mentioned at para

22.7.2(ii) and (iii) viz. retail sales data of formulations of bulk drugs as reported by the ORG. Therefore Mr. Chagla contended that this would be

against all the canons of construction. The term ""turnover"" must necessarily be given the same meaning when used in the different sub-paragraphs

of paragraph 22.7.2 of Drug Policy, 1994.

18. Further, Mr. Chagla submitted that the ORG Sales Data is a recognised database for the retail sales of formulations in the country and is

accepted as determinative even by the Drug Policy 1994 itself. It is further submitted that the turnover of bulk drugs can and has been derived by

working backwards from ORG sales data. This ORG Sales data ignores sales to hospital, Government Organisations Exports etc., since

presumably such data is not a part of the data of drugs sold in the trade channel and therefore not an index of usage. It is further submitted that the

first Respondent Union of India has itself adopted such a method and an example is the case of Norfloxacin which has been included in DPCO

1995 where the turnover for the bulk drug of about Rs. 500 lacs was computed by working backwards from the retail sales turnover of

formulations as taken from ORG data for the period ending in March, 1990.

19. Mr. Chagla further submitted that a contextual and purposive interpretation of the term ""turnover"" as used in the Drugs Policy 1994 should be

adopted and that this Court should take into account the objectives and purposes of the Drug Policy 1994 and the setting and context in which the

term ""turnover"" is used therein to give it a colour and meaning. The petitioners further submit that the term ""turnover"" cannot be read in isolation

from its context nor can different meanings be attributed to the said term in respect of its use in different parts of the criteria as set out in para

22.7.2. It is contended that taking the aggregate production along with the imports cannot be the correct computation of turnover. Turnover

requires conversion of the aggregate turnover of formulations into turnover of bulk drugs and what is required to be established is to determine the

usage of the drug in the country. It is therefore contended that based on the accepted principles of Cost Accounting and Audit Rules, turnover, in

the context in which it is used under the Drugs Policy 1994, must necessarily mean ""Imports and Domestic Production (opening stock less closing

stock) less exports.

20. Mr. Chagla, the learned counsel for the petitioner then contended that Drug Ciprofloxacin would today not satisfy the criteria for inclusion

under para 22.7.2. Further, he submitted that today there are 47 producers of the bulk drug and 117 formulators far in excess of the 5 bulk drug

producers and 10 formulators as required by para 22.7.2 (iii). Thus, today, Ciprofloxacin would in any event be excludable from price control as

per the established criteria under para 22.7.2 (iii) of Drug Policy, 1994.

21. The learned counsel on behalf of the petitioners further submitted that the entire decision making process whereby drugs have been included or

excluded in the First Schedule to DPCO 1995 has been arbitrary, irrational and not based on the said criteria and is therefore ultra vires and

without the authority of law. It is further submitted that as a result of representations made in respect of 19 bulk drugs which were wrongly included

in the First Schedule the Respondents had established a Committee of Experts (the M. M. Sharma Committee) to consider and review the lists of

drugs included in the First Schedule. These representations included representations in respect of Ciprofloxacin and Mefenamic Acid. Ranbaxy

also made its representations to the M. M. Sharma Committee by its letter dated 27th February, 1996. Despite the aforesaid, a price fixation

order dated 3rd April, 1996 was issued in the case of Ciprofloxacin even before the M. M. Sharma Committee could decide Ranbaxy''s

representations.

22. Mr. Chagla pointed out that in Writ Petition No. 569 of 1996 this Court had passed an interim order on 10th December, 1996 in which a

statement was made in an affidavit filed on behalf of the Respondents which referred to the constitution and the ongoing work of the M. M.

Sharma Committee. This Court has held that implicit in the statement referred thereto, was an understanding that the Respondents would not fix the

price of the bulk drugs pending determination by the M. M. Sharma Committee. Reference to the aforesaid, has been made by the petitioners in

para 5 of the present Writ Petition. It appears that the Respondents had first filed an affidavit dated 16th September, 1996 to oppose admission of

the present Writ Petition and in para 5 thereof dealt with the aforesaid, and inter alia had stated that ""there was no nexus between the process of

fixation of the prices of bulk drugs and the examination of inclusion/exclusion of bulk drugs by the Expert Committee which was a policy matter

and both the issues were independent and separate."" It appears that the identical contentions were reiterated in the main affidavit in reply dated

18th July, 2000. It is submitted by the petitioners that these affidavits suggest that far from considering the representations made by various

manufacturers including Ranbaxy, the M. M. Sharma Committee had in fact been disbanded by the Respondents in May, 1996 after having held

five sittings. According to the petitioners, the said M. M. Sharma committee could not make any recommendations as full data required by it was

not furnished to it by the Respondents. The petitioners have contended that, not only the aforesaid M. M. Sharma Committee was disbanded, but

the Respondents further did not for over three years after the said Drug Policy 1994, establish the National Pharmaceutical Pricing Authority

(NPPA) as contemplated by the said Policy. The NPPA was finally notified by a resolution dated 29th August, 1997 and it actually commenced

work only in or about October, 1997.

23. Mr. Chagla contended on behalf of the Petitioners that significantly, however, the Respondents even after finally constituting the NPPA on 29th

August, 1997 had sought to pre-empt its functioning by deleting the bulk drug Mefenamic Acid and Amikacin Sulphate (in respect of which

representations had been pending for over 15 months) from the First Schedule to the DPCO 1995 on or about 2nd September, 1997 i.e. before

the NPPA could consider these. These two drugs were two of the drugs in respect of which representations had been made to M. M. Sharma

Committee. The sales turnover of Mefenamic Acid between 1988 and 1992 was over Rs. 400 lakhs. The import value of Amikacin Sulphate in

1989-90 was Rs. 350 lakhs which rose to Rs. 475 lakhs in 1990-1991 and touched a level of Rs. 845 lakhs in 1992-1993. It is further submitted

that there are only two formulations of these drugs in the market and a single formulator has market share in excess of 40%.

24. The learned Counsel Mr. Chagla has contended that the arbitrary inclusion/exclusion of bulk drugs by the Respondents on a ""pick and choose

basis discloses a hostile discrimination, subjectivity and a lack of transparency. It is further submitted that the objective of transparency has also

been observed only in its breach. It is submitted by the petitioners that the Respondents have acted on the basis of the findings of a so called

Turnover Group"" which consisted of officers in the Ministry of Chemicals and Fertilizers. Neither the petitioners nor any others in the Industry had

been given a hearing by the Turnover Group, and it is further stated that the Turnover Group has not even considered the various representations

made including the Ranbaxy. No details or particulars of the data has been considered by the Turnover Group nor any copy of the report of the

Turnover Group has been furnished to the petitioners despite requests from time to time. It is further submitted that the petitioners have been

denied relevant data which was with the Respondents relating to production, exports and imports, and that no particulars or data considered by the

Expert Group on Turnover Issues of the Standing Committee"" constituted by the Respondents prior to the DPCO 1995 had been made available

to the petitioners. It is the case of the petitioners that the Respondents have also not furnished all the documents and reports on the basis of which

drugs were included in the First Schedule. It is the contention of the petitioners that the petitioners had addressed about sixteen letters to the

Respondents between January, 1995 and November, 1996 but none of the letters were replied to.

25. Mr. Chagla, the learned counsel for the petitioners made it explicitly clear that what the petitioners are seeking is only a judicial review of the

arbitrary, irrational and illegal inclusion of Ciprofloxacin in the First Schedule to the DPCO 1995. Review is not sought in respect of fixation of the

price thereof. However, there is no bar to such a judicial review, according to the petitioners. Relying on the decision of the Supreme Court in

Union of India (UOI) and Another Vs. Cynamide India Ltd. and Another etc., , it is submitted that even in a case of price fixation the price fixed

could be questioned in a Court on the ground of arbitrariness or that the consideration stipulated by the said Order as relevant were not taken into

account or that irrelevant considerations were not kept out for the determination of the price. It is submitted that the Court could inquire into

whether the policy and the guiding factors for price fixation were present in the mind of the authority. It is the submission of the petitioners that the

principles laid down in the aforesaid Cyanamid case do not restrict judicial review by a Court of the wrongful inclusion of a drug under price

control, which is a non legislative and an administrative act.

26. In Writ Petition No. 3031 of 1996 USV Limited and Anr. v. Union of India and Ors. and in Writ Petition No. 5219 of 1996 USV Limited

and Anr. v. Union of India and Ors., Mr. Rohit Kapadia, the learned Counsel for the petitioners has submitted that the petitioner USV limited is a

100% domestic concern carrying on the business, inter alia, of the manufacture and sale of diverse pharmaceutical products. By Writ Petition No.

3031/96 the petitioners are challenging the inclusion of a bulk drug called ""Doxcycline"" at Item No. 26 in the Schedule to the Drug Price Control

Order, 1995 (DPCO 1995) and by Writ Petition No. 5219/96 the petitioners are challenging inclusion of a bulk drug called ""Glipizide"" at Item

No. 57 of the DPCO 1995. The main grounds of challenge to the inclusion of the aforesaid two drugs in the First Schedule to DPCO 1995 are

that the inclusion of the said drugs is contrary to the policy issued by the Government of India in the form of New Drug Policy 1994, that the

inclusion of the aforesaid bulk drugs in the First Schedule to DPCO 1995 is completely arbitrary and based on criteria that are completely

irrelevant and the same has been done demonstrably without any application of mind. The petitioners contend, so far as drug Doxycycline is

concerned, the said drug does not even figure in the various drugs considered by the ""Standing Committee"" for inclusion/exclusion. And that so far

as Glipizide is concerned, similarly placed drugs in the same therapeutic segment as Glipizide are kept out and there is a patent and hostile

discrimination in including the bulk drug, Glipizide, within the purview of price control.

27. Mr. Rohit Kapadia on behalf of the petitioners has contended that DPCO 1995 was issued in exercise of the powers conferred u/s 3 of the

Essential Commodities Act, 1955 and was based on the New Drug Policy issued on 15th September, 1994, Prior to the same, the Drug Policy of

1986 coupled with the Drug Price Control Order 1986 which was in force, and the main objects of the Drug Policy, 1986 were to ensure

abundant availability, at a reasonable price all essential and life saving and prophylactic medicines of good quality, to strengthen the system of

quality control over drug production and to promote the rational use of drugs in the country, to create an environment conducive to channelising the

new investment into the pharmaceutical industry to encourage cost-effective production and to introduce new technologies and new drugs, and to

strengthen the indigenous capability for production of new drugs. Therefore, according to the petitioners, the purpose of the drug policy has always

been to ensure availability of quality drugs at reasonable prices within our country.

28. Mr. Kapadia submitted that on behalf of the petitioners that the Government had acknowledged the arbitrariness and lack of transparency in

the inclusion/exclusion of bulk drug prevailing under the Drug Policy 1986. It is further submitted by the petitioners that the Government had

decided to modify the Drug Policy 1986 and in the light of paragraph 9 of the New Drug Policy the criteria for inclusion/exclusion of bulk drug

were laid down in paragraph 22.7.2. paragraph 9 of the New Drug Policy reads as under :--

Pricing : The aberrations, which have come to notice, in the list of drugs and their categorization for the purpose of price control, need to be

eliminated by the use of transparent criteria applied across the board of all the drugs with minimum use of subjectivity. The high turnover of a drug

is an index of its extent of usage and is considered to meet the requirement of objectivity justifiable on economic considerations. However, the

monopoly situation in case of drugs with comparatively lower turnover has also to be kept in view. Also, as an experimental measure, drugs having

adequate competition may not be kept under the price control and if this proves successful, it would pave the way for further liberalization. In the

event, however, prices of these drugs not remaining within reasonable limits, the Government would reclamping price control.

So far as paragraph 22.7.2 of new Drug Policy 1994 is concerned, it reads as under:--

22.7.2. Span of Control

(i) The criteria for including drugs under price control will be the minimum annual turnover of Rs. 400 lacs;

(ii) Drugs of popular use in which there is a monopoly situation will be kept under Price Control. For this purpose, if for any bulk drug having an

annual turnover of Rs. 100 lacs or more there is a single formulator having 90% or more market share in the retail trade (as per ORG) a monopoly

situation would be considered as existing.

(iii) Drugs in which there is sufficient market competition, viz. at least 5 bulk drug producers and at least 10 formulators and none having more than

40% market share in the retail trade (as per ORG) may be kept outside the Price Control. However, a strict watch would be kept on the

movement of prices as it is expected that their prices would kept in check by the forces of market competitors. The Government may determine

the ceiling level beyond which increase in price will not be permissible.

(iv) Government will keep a close watch on the prices of medicines, which are taken out of price control. In case, the price of these medicines rise

unnecessarily, the Government would take appropriate measures, including reclamping of price control; (v) For applying the above criteria, to start

with, the basis would be the data upto 31st March, 1990 collected for the exercise of the review of the drug policy. The updating of the data will

be done by the National Pharmaceutical Pricing Authority as detailed in paragraph 22.7.4(i);

(vi) Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under

Price Control for 5 years from the date of manufacture in India.

29. Mr. Kapadia, the learned counsel further submitted on behalf of the petitioners that an analysis of the above span of control laid down in

paragraph 22.7. 2 read in the context of the policy contained in paragraph 9 of the New Drug Policy, would result in a turnover of Rs. 400 laps

which would be used as a yardstick. It is submitted that a minimum annual turnover of Rs. 400 lacs as on 31st March, 1990 was the

yardstick/bench mark adopted by the Government for including a bulk drug under price control, and therefore, under Clause 22.7.2(i) if there was

a bulk drug whose annual turnover as on 31st March, 1990 was Rs. 400 lacs or more, then prima-facie the drug would become eligible for

inclusion, and conversely, in respect of a drug if the annual turnover was less than Rs. 400 lacs as on 31st March, 1990 then prima-facie the drug

was eligible for being excluded from Price Control. However, it is further submitted by the petitioners, that as an exception to the above, there may

be a bulk drug whose turnover is less than Rs. 400 lacs, but such a bulk drug may still be under Price Control if a monopoly situation exists qua the

said bulk drug. A monopoly situation would exist if for a particular bulk drug there is a turnover of Rs. 100 lacs or more by a single formulator

having 90% or more market share in the retail trade as per ORG figures. Accordingly, it is submitted by the petitioners that even though there may

be a single manufacture having 100% market share, but if the turnover of the bulk drug has on 31st March, 1990 was less than Rs. 100 lacs, a

monopoly situation would not exist and such a drug would remain outside purview of price control and would not be included in DPCO 1995.

Similarly, as an exception to the benchmark of Rs. 400 lacs above, drugs in which the turnover as on 31st March, 1990 was more than Rs. 400

lacs they may still be kept out of the purview of price control if there was sufficient market competition qua the said bulk drug. Sufficient market

competition would exist if there are at least 5 bulk drug producers and at least 10 formulators and none of them have more than 40% market share

in retail trade as per ORG. The clear purport behind the above is that the Government itself acknowledges that market forces themselves are

capable of controlling the prices.

30. According to Mr. Kapadia, the word ""turnover"" has not been defined in the New Drug Policy 1994 and it has to be given a meaning that is

normally and customarily understood in the commercial field. Keeping in mind the objective of the New Drug Policy, 1994 and keeping in mind the

common sense meaning of the phrase ""turnover"" it is contended that the phrase ""turnover"" can only mean ""sales turnover"" and nothing else.

According to the petitioners, the phrase turnover can never be compared to ""production"", and that the phrase production is something, which is

wider than sales turnover. It is submitted that when a particular bulk drug is produced some of it may be wasted and some of it may be destroyed,

and some of it may be kept as stock-in-trade and some of it may even be used in the company itself besides some of it being exported. Such

quantities of bulk drugs which are not sold in India and therefore, such quantities of the bulk drug though produced, have no effect whatsoever to a

consumer and can never be encompassed under the phrase ""turnover"" and only such bulk drug that is sold in India can come within the purview of

the phrase ""turnover"". It is the contention of the petitioners that keeping in mind the objective of the New Drug Policy and the parent legislation

under which the policy is introduced namely the Essential Commodities Act, the phrase ""turnover"" should and can only mean the ""sales turnover

with regard to the sales in India, and for the purpose of New Drug Policy the figures of the sales of drug made outside India namely export sales

are necessarily to be excluded in arriving at the ""turnover"". It is further submitted by the petitioners that it would be better for the economy of our

Country if our producers can export and sell drugs to countries outside India at higher prices so as to earn precious foreign exchange and for that

purpose the Drug Policy is not to have price control outside India, and in the phrase ""turnover"" as appearing in the New Drug Policy exports have

necessarily to be excluded.

31. Mr. Kapadia further submitted that for calculating the turnover of a bulk drug, we must uniformly look only to the ORG data for the relevant

period and not to any other data. According to the learned Counsel only the ORG data is acceptable and authentic which is transparent and is

readily available to any person. According to them, the ""turnover"" of a bulk drug and the ""market share"" are intrinsically inter-related and inter-

dependent on one another. According to them, the market share is obviously arrived at on the basis of the sales turnover, and therefore, it would

be absurd to contend that though the market share of the formulation is to be calculated as per ORG data, the turnover of the bulk drug is to be

calculated on the basis of data other than ORG. Such an interpretation would be totally contrary to the avowed representation of the use of the

transparent criteria promised in the New Drug Policy, and that such a construction would be opposed to the settled rules of construction which

require that a statute or a section must be uniformly construed as a whole.

32. Mr. Kapadia submits that the phrase ""annual turnover"" can only mean domestic sales in the Country and the same cannot include the quantity

of the bulk drug exported out of India as is sought to be contended by the Government. It is the submission of the petitioners that the effect of

including exports in the phrase ""turnover"" under the span of control would lead to a situation which is not only absurd but will also be detrimental to

the economic interests of the Country.

33. Mr. Kapadia further submitted on behalf of the petitioners that so far as drug Doxycycline is concerned, the criteria for inclusion is not satisfied.

According to the petitioners as per the ORG data as on 31st March, 1990 the annual turnover of it amounted to Rs. 316 lacs, and at the relevant

time, there were at least 19 formulators and none of these formulators had more than 40% market share in the retail trade. According to the

petitioners, as per the ORG data there was no bulk drug producer selling Doxycycline in the country. Ranbaxy was the only manufacturer

manufacturing Doxycycline but it captively consumed the same, and all other formulators of Doxycycline relied only on imported bulk drug

Doxycycline. It is further submitted that as on date there are 34 formulators of Doxycycline none having more than 40% market share as per retail

trade, and besides, there is no manufacturer of the bulk drug Doxycycline today and only formulations are available in the market. It is further

submitted by the petitioners that so far as the drug Glipizide is concerned, the criteria for inclusion is not satisfied. According to the petitioners, as

per the ORG data, the annual turnover of the bulk drug Glipizide as on 31st March, 1990 was merely Rs. 82 lacs, and even if the contention of the

Government that the petitioner as the only manufacturer of the bulk drug Glipizide having a 100% market share is found to be correct (which is

denied by the petitioner) still, the turnover of the said drug is falling below Rs. 100 lacs, the monopoly situation envisaged under paragraph 22.7.2

(ii) does not apply and hence the said drug requires to be kept out of the purview of price control.

34. Mr. Kapadia therefore submitted on behalf of the petitioners that the entire decision making process in the inclusion and exclusion of drugs has

been arbitrary, irrational and not based on the relevant criteria and is therefore ultra vires, illegal and bad. According to the petitioners, as a result

of the representations made by diverse manufacturers, a Committee headed by Prof. M. M. Sharma was constituted for the review of the

exclusion of 19 drugs from the DPCO 1995. One of the drugs involved was Doxycycline in respect of which the petitioners had made

representations dated 10th March, 1995 and 26th February, 1996. The petitioners have further submitted that pending the reconsideration by the

said Sharma Committee, the prices have been fixed. The Government, in Writ Petition No. 569 of 1996 (which deals with the inclusion of a drug

called Mefenamic Acid), has filed an affidavit stating that a final decision on the representations will be taken after the recommendations of the

Sharma Committee. However, in spite of the above, the Government has fixed the prices in respect of drugs included amongst the 19 drugs

pending their reconsideration. Pending the representation of the petitioners in respect of Doxycycline, the Government has proposed to fix prices in

respect of the Doxycycline. It is further submitted on behalf of the petitioners that the Sharma Committee has been disbanded in May, 1996 after

having held six sittings and it is understood that the said Sharma Committee has not made any recommendations. It is further learnt by the

petitioners that without any recommendations being there from the said Sharma Committee, the Government has removed two drugs viz.

Mefenamic Acid and Amikacin Sulphate from the first Schedule even though they are required being included under the first Schedule, as per their

own criteria.

35. The learned counsel Mr. Kapadia on behalf of the petitioners submitted that the conduct of the Government is dishonest. Being apprehensive

that the Government will also fix price in respect of the bulk drug Glipizide, the petitioners had filed the said petition and on 18th October, 1996

had actually moved for urgent ad-interim reliefs. However, the Government at that time had opposed the application for ad-interim relief on the

ground that the apprehensions of the petitioners were unfounded as there was no decision to fix any prices and accordingly ad-interim reliefs were

refused to the petitioners. It appears that on 22nd October, 1996 the petitioners had learnt that the Government had on 18th October, 1996 fixed

the price in respect of Glipizide. This fact was however not disclosed to the Court and on the contrary an altogether a different impression was

given to the Court, which necessitated an amendment of the petition and which was granted by this Court.

36. It is further submitted on behalf of the petitioners that from the affidavit filed by the Government in Writ Petition No. 3031 of 1996, particularly

from paragraph 7, it appears that the New Drug Policy which was first introduced in September, 1994 and that the Government has formed the

Standing Committee"" which would be entrusted with the task of compiling data for the purpose of ascertaining whether the turnover of a bulk drug

exceeded 400 lacs by keeping the objectives of the New Drug Policy in mind, and that the said Standing Committee has given a recommendation

that the turnover of Doxycycline was over 400 lacs. It is submitted by the petitioners that from the limited inspection given to the petitioners of the

alleged ""Standing Committee Report"" it was revealed that the Government had announced constitution of a ""Standing Committee on 5th February,

1990 to consider all matters connected with the review of DPCO 1987; that to assist the above standing committee, three Expert Groups viz.

Group I (Therapeutic Issues) Group II (Technology Issues) and Group III (Production and Turnover Issues) were set up and these groups were to

examine all issues concerning DPCO 1987; that the said Group held 15 meetings and considered various drugs to be included/excluded in

Schedule II of DPCO 1987; that keeping the objective of the 1986 drug policy, Group III had made certain recommendations which were

contained in the report produced for inspection. It was also revealed that for the purposes aforesaid, the said Group III had considered several

drugs (307 to be precise) as stated in the table contained in the said recommendations under the heading ""Issues considered"" and sub heading ""List

of Drugs Considered by the Group"" and that in the aforesaid list of drugs apparently considered by the said Group III, the drug Doxycycline was

not included.

37. It is therefore the submission of Mr. Kapadia that the Government is now trying to confuse and mislead this Court by making a reference to the

alleged recommendation of the alleged Standing Committee Report. According to the petitioners, no Standing Committee was set up by the

Government pursuant to the New Drug Policy so as to consider/recommend data keeping in mind the objectives of the New Drug Policy, and that

the report relied upon by the Government was not a report of the Standing Committee but was a report of the Expert Group III (Production and

Turnover Issues) which was set up to assist the Standing Committee, and that the report on which the Government had relied upon had been

prepared by keeping in mind the objectives not of the New Drug Policy, but of the 1986 Drug Policy. It is further submitted by the petitioners that

whilst preparing the report of the Group III, which has been relied upon by the Government, the drug Doxycycline has not even been considered.

38. Mr. Kapadia submitted on behalf of the petitioners that the petitioners had repeatedly called upon the Government to produce the report of the

Group III that is heavily relied upon by the Government, however, the Government has chosen to ignore the aforesaid requests for the reasons not

far to see. According to the petitioners, the fact that the Government itself is refusing to produce, the said report in Court leads to an inference that

the Government is fully aware of the discrepancies contained therein.

39. Mr. Kapadia further submitted that on behalf of the petitioners that all the anti-diabetic drugs are removed from the purview of the DPCO 95

with the exception of Insulin and Glipizide. Glibenclamide which initially was included in the DPCO 1987 was subsequently excluded under the

DPCO 1987 itself and continued to remain excluded from the DPCO 1995. According to the petitioners the only other anti-diabetic drug included

in the DPCO 1995 is Insulin. A chart shown at Exhibit G-I to the petition shows the list of anti-diabetic drugs which were originally included under

price control but have now been excluded, to the arbitrary exception of the bulk drug Glipizide. According to the petitioners, as per the ORG data

the annual turnover of Insulin as on 31st March, 1990 was Rs. 441 lakhs and consequently Insulin squarely came within the purview of price

control under para 22.7 of the New Drug Policy and the only other bulk drug in the therapeutic group of anti-diabetic drugs included in the DPCO

1995 is Glipizide even though its annual turnover was only Rs. 82 lacs. According to the petitioners, thus, such an inclusion of Glipizide in the first

Schedule to the DPCO 1995 to the exclusion of all other similar drugs amounts to a clear hostile and invidious discrimination and the same is ex

facie ultra vires of Article 14 of the Constitution of India. It is further submitted on behalf of the petitioners that as far as anti-diabetic drugs having

an annual turnover less than Rs. 100 lakhs are concerned, irrespective of market share, not a single drug, except Glipizide is included in the DPCO

1995. It is therefore, submitted on behalf of the petitioners that the inclusion of the above two bulk drugs is erroneous and accordingly the

petitioners contend that their petitions should be made absolute with costs.

40. Mr. Cooper, the learned counsel for the petitioners submitted that as far as Writ Petition No. 1749 of 1999 is concerned which deals with the

drug Salbutamol, the turnover of drug at the relevant time was Rs. 171.17 lakhs as such the drug does not meet the criteria as per para 22.7.2(i)

for being included in the drug price control. Mr. Cooper also submitted that as far as drug Salbutamol is concerned, there is a substantial market

competition inasmuch as there are 5 bulk drug producers and 23 formulators at the relevant time and that no company having a market share of

more than 40% in the retail trade as per the figures given by ORG. In view thereof even the said drug also meets the criteria as contemplated under

para 22.7.2 (iii) and as such, the said drug gets excluded from the price control. Mr. Cooper has contended that the relevant data given

hereinabove were for the period ending on 31st March, 1990.

41. In the same petition as far as the other drug viz. Theophylline is concerned the market competition is with 6 bulk drug producers and 31

formulators and no company is having the market share of 40% in the retail trade as per ORG figures and as such the drug Theophylline meets

criteria as per para 22.7.2(iii) for being excluded from price control. These figures are also based on data as on 31st March, 1990.

42. As far as Writ Petition No. 1974 of 2000 is concerned Mr. Cooper has contended that the drug involved in the said Writ Petition is

Ciprofloxacin with a turnover of Rs. 243.05 lakhs and as such the drug does not meet the criteria under paragraph 22.7.2(i) for being included in

price control.

43. As far as Writ Petition No. 2019 of 2000 is concerned the drug Norfloxacin with a market competition of 28 bulk drug producers and 20

formulators with no company having a market share of 40% as per the figures of ORG, therefore, the same meets criteria under paragraph

22.7.2(iii) for being excluded from price control and these figures are also based on data as on 31-3-1990.

44. As far as Writ Petition No. 2051 of 2000 is concerned the drug concerned is Cloxacillin and with a market competition of 16 bulk drug

producers and 23 formulators and that no company is having 40% retail trade as per ORG figures as such the same meets the criteria under

paragraph 22.7.2(iii) for being excluded from price control and the data is based on 31-3-1990.

45. As far as Writ Petition No. 2060 of 2000 is concerned the name of the drug Cloxacillin with a market competition of 16 bulk drug producers,

23 formulators with no company having a market share of over 40% in the retail trade as per ORG figures, and as such meets the criteria as per

22.7.2(iii) for being excluded from price control and the data is dated 31-3-1990.

46. With regard to Writ Petition No. 1758 of 2000 the drug involved is Cloxacillin with a market competition of 16 bulk drug producers and 23

formulators with no company having market share of over 40% in the retail trade as per ORG figures. Hence it meets criteria under paragraph

22.7.2(iii) for exclusion from drug price control and the data is as on 31-3-1990.

47. Mr. Cooper referred to a judgment of Karnataka High Court with regard to a similar issue as involved in these petitions:in the case of Remidex

Pharmaceuticals Private Limited, Bangalore and another Vs. Union of India and another, wherein the Kamataka High Court has deprecated that

the Government had not kept in mind all the relevant materials in the decision making process. It is also held that the Government has not bothered

to collect, before fixing the price, all the necessary materials required in the decision making process. Therefore, Karnataka High Court has held

that the Government has kept out of consideration the relevant materials needed to form an opinion at the material stage. In para 19 of the said

judgment the Karnataka High Court has clearly ruled that there is nothing on record to show that such an inquiry was undertaken before working

out the formula and as such the Government had eschewed all the relevant materials in the decision making process.

48. As far as the aspect of ""turnover"" is concerned, Mr. Cooper has contended that the ""turnover"" is not defined in the DPCO. However, the

word ""Sale Turnover"" is defined in Section 2(w) of the DPCO to mean product of units of formulations sold multiplied by the retail price.

Therefore, Mr. Cooper contended that the concept of ""turnover"" is well understood in the context of various taxing statutes especially the sales tax,

that is to say total amount of goods sold. The learned Counsel Mr. Cooper has contended that as the word ""turnover"" can never be equivalent to

the quantum of drug ""produced"" and ""turnover"" can only mean the quantum of drug sold and not produced. Therefore, the learned counsel

contended that if something is produced but not sold it can never be taken into the concept of ""turnover"" that is to say the goods are produced but

same cannot be sold either there is no market or for any other reasons then they cannot enter into the concept of ""turnover"". Therefore, the goods

which are produced and lying as stock in trade can never form part of the ""turnover"" of that product. Similarly the learned counsel has also

emphasised the word ""production"". This concept which is relevant when deciding upon the quantum of manufacture. The same can become

relevant for the purposes of excise which is a tax on manufacture of goods. This can never be in a commercial or legal sense amount to ""turnover"".

Therefore, Mr. Cooper contended that the general turnover can only mean sales ""turnover"" and not production turnover. Therefore, Mr. Cooper

referred to Clause 27.7.2 of the DPCO which refers to only ""turnover"" of sales and it obviously will have to exclude export. Mr. Cooper also

pointed out that the word ""turnover"" in Sub-cause (i) refers to sale. Similarly in Sub-clauses (ii) and (iii) refer exclusively of retail trade and which

will have to be determined with reference to ORG figures.

49. Mr. Cooper contended that according to the Respondents that the imports must be included in determining turnover. Therefore, if that were to

be so, logically production is not the criteria for determining the ""turnover"". The criteria is the amount of units of drug which find a way into the

various formulations and are sold in the market in India. Therefore, Mr. Cooper has contended that whatever formulations which are for domestic

consumption which could only be converted into formulations sold.

50. Mr. Cooper thereafter referred to and relied on a detailed interlocutory order dated 10th December, 1996 passed by Division Bench of this

Court wherein it has been observed as under :--

10. It is thus clear to us in the light of the objectives of the Drug Policy as set out in Para 1 of the Introductory Chapter of New Drug Policy

(reproduced in para 3 above) that the experts will have to be excluded while arriving at the figure of minimum annual turnover Admittedly that has

not been done. The basis for calculating the annual minimum turnover of 400 lakhs as per Clause (i) of 22.7.2 has not been the actual sale figures

as per ORG but some other hypothetical calculation based on the cost of production and cost of imports by adding notional import duty of 10.5%

as set out in para 5 of the Executive Summary reproduced above in para 9. Prima facie, therefore, in our view, there is failure to take into account

the relevant material while applying the first criterion for imposing the price control and further irrelevant considerations have been taken into

account for exercising the said power.

51. Mr. Cooper, thereafter, pointed out that even the modifications made in the drug policy of 1986 were also mainly for local market and not for

export at all. Mr. Cooper has also pointed out that there is no specific denial by the * Respondents in their affidavit in reply with regard to the

factual data given in each of the petitions pointed out as to how these drugs are to be excluded from the purview of Drugs Price Control. Under

these circumstances, Mr. Cooper the learned counsel has contended that the Respondents action of bringing the aforesaid drugs within DPC is

totally arbitrary, irrational and illegal. Mr. Cooper has contended that even factually these drugs could never have been brought under price control

even as per existing policy apart from the fact that the action of Respondents'' bringing the drugs within DPC is without any application of mind and

as such contended that ail the petitions should be allowed.

52. Mr. Chagla, the learned counsel appearing in Writ Petition No. 3449 of 1996 had pointed out that the drug involved was Ciprofloxacin and

the said drug could not have been covered within the DPCO and in fact it appears that on 2nd September, 1997 the necessary exemption was

also granted. Mr. Chagla also contended that what is relevant is to bring within the DPCO is only the local consumption or sales figure and the

Respondents should not at all be concerned with the export figures inasmuch as the DPCO applies only with regard to local consumers and the

DPCO of no relevance with regard to a foreign buyer. In fact Mr. Chagla contended that if the price of the drug were to be more as far as foreign

buyers are concerned, it would be better in the sense India would earn more foreign exchange and thus DPCO need not be made applicable for

the drugs which have been exported. In fact such an interpretation would be deleterious to Indian economy in the sense Indian Government would

not be earning sufficient foreign exchange. Mr. Chagla referred to a judgment of the Apex Court with regard to principles of the interpretation in

State of West Bengal Vs. Union of India, wherein the Supreme Court has observed as under:--

But the rule that the State is not bound, unless it is expressly named or by necessary implication in the statute is one of interpretation. In

considering the true meaning of words of expression used by the Legislature the Court must have regard to the aim, object and scope of the statute

to be read in its entirety. The Court must ascertain the intention of the Legislature by directing its attention not merely to the clauses to be construed

but to the entire Statute; it must compare the clause with the other parts of the law, and the setting in which the clause to be interpreted occurs.

53. Thereafter Mr. Chagla referred to another judgment of the Apex Court in Reserve Bank of India v. Peerless G. F. and I. Co. Ltd., AIR 2987

SC 1023 wherein the Supreme Court has laid down the principle of interpretation as under:--

33. Interpretation must depend on the text and the context. They are the bases of interpretation. One may well say if the text is the texture, context

is what gives the colour. Neither can be ignored. Both are important. That interpretation is best which makes the textual interpretation match the

contextual. A statute is best interpreted when we know why it was enacted. With this knowledge, the statute must be read, first as a whole and

then section by section, clause by clause, phrase by phrase and word by word. If a statute is looked at, in the context of its enactment, with the

glasses of the statute-maker, provided by such context, its scheme, the sections, clauses, phrases and words may take colour and appear different

than when the statute is looked at without the glasses provided by the context. With those glasses we must look at the Act as a whole and discover

what each section, each clause, each phrase and each word is meant and designed to say as to fit into the scheme of the entire Act. No part of a

statute and no word of a statute can be construed in isolation. Statutes have to be construed so that every word has a place and everything is in its

place. It is by looking at the definition as a whole in the setting of the entire Act and by reference to what preceded the enactment and the reasons

for it that the Court construed the expression ""Prize Chit"" in Srinivasa and we find no reason to depart from the Court''s construction.

54. Mr. Chagla referred to another judgment of Supreme Court in Home Secretary, U.T. of Chandigarh and Another Vs. Darshjit Singh Grewal

and Others, . wherein the Supreme Court has held that when a policy is initiated for general application then the administration is bound by it. It can

of course change the policy but until it is changed, it is bound to adhere to the policy. In a similar line in State of Bihar and Others Vs. M/s.

Suprabhat Steel Limited and Others, the Supreme Court has held that a policy will have to be followed unless the same is revised.

55. Mr. Chagla then referred to Punjab Communications Ltd. Vs. Union of India and Others, with regard to substantive legitimate expectation in

the sense, the change in a policy can defeat a substantive legitimate expectation if it can be justified on the principle of Wednesbury reasonableness.

Therefore, Mr. Chagla has contended that the petitioners and such other manufacturers had a substantive legitimate expectation that there could be

no change in the policy unless this change in the policy could be justified by the concept of aforesaid reasonableness and in the instant case the

Respondents have failed to show any such justification whatsoever.

56. Mr. Chagla thereafter finally referred to a judgment of the Supreme Court in M/s. Shri Sitaram Sugar Co. Ltd. and another Vs. Union of India

and others, wherein the Apex Court was dealing with price control of sugar, wherein, in para 25, the Supreme Court has clearly held that the price

of sugar must be determined by the Central Government having regard to the factors mentioned in Clauses (a) to (d) of Sub-section (3-C). This is

done with reference to the industry as a whole and not with reference to any individual seller. In contradistinction to the ""price of sugar"", the

amount is calculated with reference to the particular seller. The Central Government is authorised to determine different prices for different areas

or for different factories or for different kinds of sugar. In the said judgment the Supreme Court has also interpreted the words ""having regard to"".

These words are not a fetter or words of limitation but for a general guidance to make an estimate.

57. Mr. Harish Salve, the learned Solicitor General of India appearing for the Respondents sought to contend that in the instant case the petitioners

have been rightly brought within the purview of the DPCO 1995. Mr. Salve contended the word ""turnover"" will have to be given a natural meaning

and as per the Webster''s dictionary the word ""turnover"" is not restricted to the domestic sales alone. In that context the learned Solicitor General

had referred to and relied upon a judgment of the Apex Court in George Oakes (Private) Ltd., Addison and Co. (Private) Ltd. and Rane

(Madras) Ltd. Vs. State of Madras, wherein the word ""turnover"" has been interpreted and the Supreme Court has held that the word should not

be given a restricted meaning. Mr. Salve also referred to and relied upon another Apex Court judgment in S.A. Venkataraman Vs. The State, ,

wherein the Supreme Court has expressed caution to the effect that the Court should not substitute its own words for the words of statute as

contained in the clause of the said Statute. Thereafter Mr. Salve referred to and relied upon a judgment of the Supreme Court in Nohiria Ram Vs.

The Union of India (UOI) and Others, of the said judgment the Supreme Court "has referred to an English decision in Commissioner for Special

Purposes of Income Tax v. Pemsel, (1891) A.C. 531 (G) wherein it is held as under:--

.....that it is not competent to any Court to proceed upon the assumption that the Legislature has made a mistake. The Court must proceed on

the footing that the Legislature intended what it has said. Even if there is some defect in the phraseology used by the Legislature the Court cannot,

as pointed out in Crawford v. Spooner, 6 MOO P.C. 1(H), aid the Legislature"s defective phrasing of an Act or add and amend or, by

construction make up deficiencies which are left in the Act.

58. The learned Solicitor General thereafter, referred to a decision of the Supreme Court in British India General Insurance Co. Ltd. Vs. Captain

Itbar Singh and Others, wherein the Supreme Court has held that rules of interpretation do not permit to interpret in a manner which would be

meaningless or doubtful meaning. Similarly the learned Solicitor General referred to a judgment of the Supreme Court in Bihar Legal Support

Society Vs. Chief Justice of India and Another, , wherein the Supreme Court has held that the interpretation should be purposeful and not to

invoke other words and also that the exemption should be construed strictly. "

59. Mr. Salve thereafter brought to our notice the judgment of the Supreme Court in The Union of India (UOI) Vs. The Commercial Tax Officer,

West Bengal and Others, , wherein the Supreme Court has held in para 18 as under:--

This exemption is the creation of the statute and must be construed strictly and cannot be extended to sales to other departments. The fact that the

section was not amended until 1949 does not at all indicate that the Bengal Legislature intended to extend the benefit of the section to any but the

departments specifically mentioned in the section...

60. Mr. Salve, the learned Solicitor General of India further relied upon the judgment of the Apex Court in Union of India (UOI) and Another Vs.

Cynamide India Ltd. and Another etc., . Mr. Salve contended that the price fixation is an administrative or a quasi judicial character and as such

judicial review, over the same ought to be extremely limited. In the said judgment the Supreme Court has held that the Court cannot delve into a

question whether there has been an arbitrary assumption on facts and figures and that the Court cannot sit in appeal over the Government policy or

over a matter of price fixation. Therefore, Mr. Salve has contended that the Court should be extremely reluctant to interfere in matters of price

fixation.

61. Mr. Salve has also contended that DPCO of 1995 is only a guideline. He also contended that it is not only total sales figures that would come

within the purview of ""turnover"" but the figures of entire production. The learned Counsel contended that even export figures will have to be

included. Mr. Salve had laid a strong emphasis on the Apex Court judgment in M/s. Shri Sitaram Sugar Co. Ltd. and another Vs. Union of India

and others, wherein in para 29 the Supreme Court has held that the expression ""having regard to"" do not act as a fetter and that they are not words

of limitation, but of general guidelines to make an estimate. Even in para 30 the observations are that the words ""having regard to"" are legislative

instructions for the general guidance of the Government in determining the price of sugar. They are not strictly mandatory, but in essence directory.

It is made clear in the said judgment that reasonableness of the order made by the Government can be decided by the Court.

62. Mr. Salve referred and relied upon a judgment of the Supreme Court in The Barium Chemicals Ltd. and Another Vs. The Company Law

Board and Others, , wherein the Supreme Court has observed that even if a statutory order is passed in good faith and with the best of intention to

further the purpose of the legislation which confers the power, since the Authority has to act in accordance with and within the limits of that

legislation, its order can also be challenged if it is beyond those limits or is passed on grounds extraneous to the legislation or if there are no

grounds at all for passing it or if the grounds are such that no one can reasonably arrive at the opinion or satisfaction requisite under the legislation.

In any one of these situations it can well be said that the authority did not honestly form its opinion or that in forming it, it did not apply its mind to

the relevant facts.

63. The Apex Court in the said judgment of Shri Sitaram Sugar Co. Ltd. v. Union of India has held that any act of the repository of power,

whether legislative or administrative or quasi-judicial, is open to challenge if it is in conflict with the Constitution of India or the governing Act or the

general principles of the law of the land or it is so arbitrary or unreasonable that no fair minded authority could ever have made it. Mr. Salve has

very strongly relied on the above judgment and contended that judicial review of price fixation is not within the province Of the Courts. Judicial

intervention in respect of such matters is limited to the extent when it is found to be an irrational basis on which the conclusions were reached by

the concerned authority.

64. Mr. Salve has further contended that the ORG figures are not final and that there cannot be any automatic exclusion. Mr. Salve then contended

that if the decision making process was reasonable then this Court ought not to interfere.

65. All the learned counsel for the petitioners have contended that the Government cannot disobey its own policy and the emphasis that the

guidelines are important so as to avoid any apprehension and decision should be objective and not subjective. The learned Counsel also contended

that these guidelines should not be interpreted in a manner to discriminate only certain manufacturers. Under these circumstances the learned

Counsel for the petitioners pray that all the petitions should be allowed and the impugned actions of the Respondents ought to be struck down.

66. Mr. Cooper, the learned counsel for the petitioners in Cipla Limited and Anr. v. Union of India and Ors. (Writ Petition No. 1749 of 1999) has

contended that the Respondents had in a mala fide manner refused to issue exemption notification in an arbitrary and unjustified way to the

petitioners, which was already directed to be issued for Salbutamol and its formulations, from the price control, in view of the new process

developed by the petitioner by virtue of its indigenous Research and Development. Mr. Cooper has contended that there is ample correspondence

and documentary proof for grant of such an exemption, as mentioned in the petition. As the said issue is not involved in all the other petitions, for

the time being Mr. Cooper has not argued the above issue and has reserved his right to argue the same, if need arises. Certain other issues are also

raised in the said petition. Presently we are also not considering the said issues, as they pertain only to the above petition. It is made clear that the

said Writ Petition No. 1749 of 1999 be heard on merits on the other issues which we have not decided.

67. After hearing all the learned counsel for the parties in the above petitions, broadly the following points arise for our consideration and decision

:--

(i) Scope of judicial review with regard to the inclusion of drugs within the purview of price control ?

(ii) Interpretation of the words ""turnover"" occurring in paragraph 22.7.2 Drug Policy, 1994.

(iii) Whether all relevant factors and materials were not taken into account and irrelevant factors and materials were taken into account, while

bringing the concerned drugs within the purview of Drug Policy, 1994?

(iv) Whether the Respondents have acted wrongfully, arbitrarily and irrationally in an unreasonable manner to include the drugs manufactured by

the petitioners as mentioned in the petitions within the purview of Drug Price Control Order, 1995 ?

68. As far as the first point is concerned, regarding the scope of judicial review with regard to inclusion of drugs within the purview of price

control, the Apex Court in Union of India (UOI) and Another Vs. Cynamide India Ltd. and Another etc., has dealt with the same. In the case

before the Supreme Court, price fixation under Drug Price Control Order was challenged, as the price fixed was arbitrary and unreasonable. In

that context the Supreme Court has held that ""price fixation is neither the function nor the forte of the Court."" However the Apex Court has also

made it clear with regard to its jurisdiction in paragraph 4, as under :--

But we do not totally deny ourselves the jurisdiction to enquire into the question, in appropriate proceedings, whether relevant considerations have

gone in and irrelevant considerations kept out of the determination of the price.

69. Similarly in Cynamide India Ltd. case, the Apex Court in paragraph 31 has held as under with regard to the scope of judicial review as far as

price fixation is concerned :--

We mentioned that the price fixed by the Government may be questioned on the ground that the considerations, stipulated by the order as relevant

were not taken into account. It may also be questioned on any ground on which a subordinate legislation may be questioned, such as, being

contrary to constitutional or other statutory provisions. It may be questioned on the ground of a denial of the right guaranteed by Article 14, if it is

arbitrary, that is if either the guidelines prescribed for the determination are arbitrary or if, even though the guidelines are not arbitrary, the

guidelines are worked in an arbitrary fashion.

70. In the instant case, in all the petitions, the basic challenge is that the drugs concerned do not fall within the purview of DPCO 1995. The

challenge is also that an irrelevant factor like export sales figures are being included within the term ""turnover"", which is irrational and arbitrary

hence violative of Article 14 of the Constitution of India. In these petitions, mere is also a challenge that though some of the dings ought to have

been included within DPCO, 1995, which have been left out but the drugs manufactured by the petitioners have been wrongfully included in an

arbitrary and irrational manner. In the light of Cynamide India Ltd. case, all the above challenges squarely fall within the scope of judicial review.

Hence we hold that as far as the first point is concerned, this Court can judicially review the inclusion of drugs within the purview of price control.

71. Now the second point is the interpretation of the word ""turnover"" occurring in Drug Price Control Order, 1995. The word ""turnover"" has not

been separately defined the above DPCO 1995. However ""sale turnover"" is defined in paragraph 2(w) of DPCO 1995 as under :--

(w) ""Sale turnover"" means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year

multiplied by retail price inclusive of sales tax, if any, paid on direct sales by the manufacturer or importer but does not include excise duty and

local taxes, if any :--

72. The main objectives of the Drug Policy are to ensure abundant availability at reasonable prices all essential life saving and prophylactic

medicines of good quality, to strengthen the system of quality control over drug production and promote the rational use of drugs in the country, to

create an environment conducive to channelising new investment into the pharmaceutical industry, to encourage cost effective production with

economic sizes and to introduce new technologies and new drugs and to strengthen the indigenous capability for production of drugs. In Drugs

Policy, 1994, the special emphasis was on turnover as an index of the extent of usage of a drug and on ensuring the equitable distribution and

abundant availability of drugs of good quality as well as to introduce new technologies and new drugs in India.

73. The main contention of all the petitioners in these petitions is that ""Annual turnover"" occurring in paragraph 22.7.2(i) of DPCO, 1995, is a

reference to domestic sales turnover of the bulk drug that is to say the aggregate quantity of bulk drugs sold in the domestic market (whether

produced in India or imported from abroad) and include the quantity of the bulk drugs exported. It was also strongly emphasised that DPCO''s

have been issued u/s 3 of Essential Commodities Act, 1955, which can regulate prices of essential commodities within the territorial limits of India

and not outside the territorial limits of India. The main objective is to provide cheap drugs to; our Indian Populace and not to restrict the foreign

exchange earnings of Indian drug companies, whereby our country benefits. Even in paragraph 3(v) of the affidavit in reply of the Respondent it is

emphasised that the ""turnover"" as used in paragraph 9 of Drug Policy, 1994, "would be to determine the extent and usage of a bulk drug in the

country. Therefore export figures will have to be excluded. There is no dispute that the ORG figures pertain only to sales figures within the territory

of India. If one were to have a look at paragraph 22.7.2. of Drug Policy, 1994, both in Sub-clauses (ii) and (iii) there is a mention of retail trade as

per ORG, while dealing with annual turnover. Whereas in Sub-clause (i) of paragraph 22.7.2, one cannot add the export sales figures. This would

lead to an absurd situation. The word ""turnover"" will have to be given the same meaning in all Sub-clauses (i), (ii) and (iii) of the said paragraph

22.7.2. If one, were to include export sales figures only in Clause (i) and not in Clauses (ii) and (iii), the same would lead to an incongruous and

absurd result. The entire purpose of paragraph 22.7.2 is to prevent a monopoly situation and to allow a healthy market competition to stabilize the

price at a reasonable level. The word ""turnover"" has to be interpreted in a contextual and purposive manner.

74. The Apex Court has laid down in Reserve Bank of India Vs. Peerless General Finance and Investment Co. Ltd. and Others, the principle of

contextual interpretation in the following words in paragraph 33,

Interpretation must depend on the text and the context. They are the bases of interpretation. One may well say if the text is the texture, context is

what gives the colour. Neither can be ignored. Both are important. That interpretation is best which makes the textual interpretation match the

contextual. A statute is best interpreted when we know why it was enacted. With this knowledge, the statute must be read, first as a whole and

then section by section, clause by clause, phrase by phrase and word by word. If a statute is looked at, in the context of its enactment, with the

glasses of the statute-maker, provided by such context, its scheme, the sections, clauses, phrases and words may take colour and appear different

than when the statute is looked at without the glasses provided by the context. With those glasses we must look at the Act as a whole and discover

what each section, each clause, each phrase and each word is meant and designed to say as to fit into the scheme of the entire Act. No part of a

statute and no word of a statute can be construed in isolation. Statutes have to be construed so that every word has a place and everything is in its

place. It is by looking at the definition as a whole in the setting of the entire Act and by reference to what preceded the enactment and the reasons

for it that the Court construed the expression ""Prize Chit"" in Srinivasa and we find no reason to depart from the Court''s construction.

75. We agree with Mr. Salve that no restrictive meaning should be given to the word ""turnover"". However, one cannot forget in what context the

word ""turnover"" is used in paragraph 22.7.2, and also the purpose of the said paragraph. In that context and purpose, we have no doubt in our

mind that export sales figures cannot be included within the word ""turnover"" in paragraph 22.7.2, as the same is alien in the context and purpose of

the said paragraph.

76. The Respondents have contended that as far as the interpretation of ""turnover"" is concerned, it should include the export sales figures i.e. the

value of the entire product produced should be taken into account for the purpose of ascertaining the turnover as per the paragraph 22.7.2 of Drug

Policy, 1994. On the contrary, the learned Counsel for the petitioners have submitted that the expression ""turnover"" can only mean the domestic

sales turnover and nothing else and the same can never be compared to ""production"" and the word ""production"" is much wider than the sales

turnover, inasmuch as when a particular bulk drug is produced, some of it may be wasted, some of it may be destroyed, some of it may be kept in

as stock-in-trade and some of it may be used by the Company itself, apart from some quantity being exported. Therefore, for the price control,

only the drugs which are sold within the domestic market would be relevant, and not the quantity of drugs produced and not sold within the

domestic market. The expression ""turnover"" of the bulk drug and ""market share"" are intrinsically inter-related and inter-dependent on one another.

Therefore, the market share can only be arrived on the basis of sales turnover and that is why there is a reference of ORG data. Therefore the

expression ""turnover"" under paragraph 22.7.2 can only mean the domestic sales and nothing else. Apparently, the export sales figures are totally

irrelevant inasmuch as they do not form part of any market share. The market share as contemplated under Drug Policy, 1994 is only the share of

sales turnover"" in the domestic market and the same has nothing to do with the export or production, which figures are totally irrelevant.

77. If ""export sales figures"" have to be also taken into account with regard to ""turnover"", then even the drugs which are exported from India will

come within the price control, as a result even drugs exported will have to be sold at a cheaper rate to foreigners and India will earn much lesser

foreign exchange. On the contrary in a contextual and purposive manner if the word ""turnover"" is interpreted, the same cannot include export safes

figures.

78. Therefore, we answer the second point to hold that the word ""turnover"" occurring in paragraph 22.7.2 of Drug Policy, 1994, cannot include

any of export sales figures.

79. As far as the third point is concerned, as to whether all relevant materials were not taken into account or that irrelevant materials were taken

into account while bringing the concerned drugs within the purview of Drug Policy, 1994, there is no dispute that export sales figures were

included, while deciding to bring the concerned drugs within the purview of price control. We have already held that ""export sales figures"" are

irrelevant for the purpose of computing ""turnover"" in paragraph 22.7.2 of Drug Policy, 1994 there is no doubt that the aforesaid irrelevant materials

were taken into account while bringing the concerned drugs within the purview of price control. By doing so the Respondents have acted contrary

to their own guidelines as per Drug Policy, 1994.

80. As indicated hereinabove, that the Respondents have wrongly taken into account the value of entire production of bulk drug or formulations, as

pointed out hereinabove, some part of it may be wasted, some part of it may be damaged, some part of it may be used by the Company itself, and

apart from the above, some part may be exported, as far as for the purpose of determining whether, the drug ought to be brought within the Drug

Policy, 1994, what is relevant is only the domestic sales turnover and not the other figures. Apparently, in the instant case, the Respondents have

taken into account all the irrelevant material viz. the sales figures of production without comprehending that the same have no relevance for the

purpose of Drug Policy, 1994. Apparently all the aforesaid irrelevant material have been taken into account for the concerned drugs, and the same

have been wrongly brought within the purview of Drug Policy, 1994. Under these circumstances, we answer the third point to the effect that all

irrelevant factors and material have been taken into account while bringing the concerned drugs within the purview of the Drug Policy, 1994.

81. As far as fourth Point is concerned, whether the Respondents have acted wrongfully, arbitrarily and irrationally to include the drugs

manufactured by the petitioners as mentioned in the petitions within the purview of the Drug Policy, 1994, we have to consider the same with

regard to the facts of each petition.

82. As far as Writ Petition No. 1749 of 1999 is concerned, the drugs involved in the same are Salbutamol and Theophyline. It appears from the

pleadings that as far as the drug Salbutamol is concerned, at the relevant time the annual sales turnover was Rs. 171.17 lakhs, and as such, the

same does not meet the criteria as per paragraph 22.7.2(i) for being included in the drug price control. Another aspect to be noted herein is that as

far as drug Salbutamol is concerned, there is also a substantial market competition, inasmuch as there are 5 bulk drug producers and 23

formulators at the relevant time and that none had a market share of more than 40% in the retail trade as per the figures given by the ORG. In view

thereof, the said drug Salbutamol meets the criteria as contemplated in paragraph 22.7.2(iii) and as such, the said drug ought to get excluded from

the drug price control. The above sales figures were for the period ending on 31st March, 1990. It is pertinent to note that though the Respondents

have filed an affidavit in reply in this petition, as far as the factual details and submissions are concerned, the Respondents have not controverted

them at all. In fact, the petitioners have given the names of all the bulk drug manufacturers as well as the formulators and their respective market

shares and even there domestic sales figures. Excepting a bald denial, the Respondents have not given any details or particulars controverting the

above. Hence, we have to hold that as far as drug Salbutamol is concerned, it could not have been brought within the purview of price control as

per paragraph 22.7.2(i) of Drug Policy 1994 as at the relevant time, the domestic sales figure was only Rs. 171.17 lakhs. In any event, the said

drug Salbutamol had to be excluded from the price control, in view of the fact that there are 5 bulk drug producers and 23 formulators and at the

relevant time no one was having more than 40% share in the retail trade as per the figures given by the ORG. In the same petition, the other drug

involved is Theophyline. The petitioners have alleged that with regard to the drug Theophyline, there is a market competition of 6 bulk drug

producers and 31 formulators and no one is having market share of more than 40% in the retail trade as per the ORG figures and as such the said

drug Theophyline ought to be excluded from the drug price control as per paragraph 22.7.2(iii), The details furnished in the petition with regard to

this drug were based on the data as on 31st March, 1999 which was the relevant date. With regard to this drug also the Respondents have not

been able to controvert factually, excepting a bald denial. Under these circumstances, we have to hold that the said drug Theophyline could not

have been brought within the purview of price control and therefore same ought to be excluded as per the provisions of paragraph 22.7.2(iii) of

Drug Policy, 1994.

83. As far as Writ Petition No. 1974 of 2000 is concerned, the learned counsel for the petitioner has submitted that the drug involved in this

petition is Ciprofloxacin with a turnover of Rs. 243.05 lakhs and as such, the said drug does not meet the necessary criteria as per para 22.7.2 (i)

for being included in the price control. In March, 1990, there were 7 bulk drug producers and 22 formulators of Ciprofloxacin and today there are

47 bulk drug producers and 117 formulators of the said drug. Hence the said drug has to be excluded as per paragraph 22.7.2(iii) of Drug Policy,

1994. So far as this Writ Petition is concerned an affidavit in reply of the Respondents has been filed but there are only bald denials, and no

specific particulars and details are given to controvert the contentions of the petitioners. As per the figures indicated hereinabove, apparently, the

said drug could not have been brought within the purview of the price control. Therefore, we hold that the said drug could not have been brought

within the purview of price control, and has to be excluded from price control.

84. In Writ Petition No. 2019 of 2000 the drug involved is Norfloxacin with a market competition of 28 bulk drug producers and 20 formulators

with no one having a market share of more than 40% in the retail trade as per the ORG figures and therefore the said drug meets the criteria for

being excluded from price control under para 22.7.2{iii), and these sales figures are also based as on 31st March, 1990. So far as this Writ

Petition is concerned on affidavit in reply has been filed by the Respondents but there are only bald denials, and no specific particulars and details

are given to controvert the contentions of the petitioners. Hence we hold that the aforesaid bulk drug Norfloxacin could not be brought within the

purview of Price Control.

85. In Writ Petition No. 2051 of 2000 the drug involved is Cloxacillin with a market competition of 16 bulk drug producers and 23 formulators

and that no one is having more than 40% share in the retail trade as per the ORG figures as per the data based as on 31st March, 1990 and as

such, the same meets the criteria of para 22.7.2(iii) for being excluded from the price control. There is no affidavit in reply controverting the

aforesaid factual details and hence, we hold that the said drug Cloxacillin could not be brought within the purview of the price control.

86. In Writ Petition No. 2060 of 2000 the drug involved is Cloxacillin with a market competition of 16 bulk drug producers and 23 formulators

with no one is having a market share of more than 40% in the retail trade as per the ORG figures and as per the data based as on 31st March,

1990 and as such, the said drug meets the criteria as per paragraph 22.7.2 (iii) for being excluded from the price control. There is no affidavit in

reply controverting the factual details and hence, we hold that the said drug Cloxacillin could not be brought within the purview of the price control.

87. As far as the Writ Petition No. 1758 of 2000 is concerned, the drug involved is Cloxacillin with a market competition of 16 bulk drug

producers and 23 formulators with no one having a market share of more than 40% in the retail trade as per the ORG figures and as per the data

based as on 31st March, 1990, and as such, the said drug meets the criteria as per paragraph 22.7.2 (iii) for being excluded for the price control.

In this Writ Petition an affidavit in reply has been filed by the Respondents but there are only bald denials, and no specific particulars and details

are given to controvert the contentions of the petitioners, and hence, we hold that the said Drug Cloxacillin could not be brought within the purview

of the price control.

88. As far as Writ Petition No. 3449 of 1996 is concerned, Mr. Chagla, the learned Counsel for the petitioners has contended that the drug

involved in the said petition viz. the Ciprofloxacin was never under the price control prior to DPCO 1995. Admittedly, there are 16 bulk drug

producers and 23 formulators with no one having more than 40% market share in the retail trade as per the ORG figures, and as such, the said

drug meets the criteria as per paragraph 22.7.2(iii) for being excluded from the price control and the data is based as on 31st March, 1990. We

therefore, hold that the said drug Ciprofloxacin could not have been brought within the purview of price control. Apart from the above, Mr. Chagla

has also contended that the Respondents have acted in an arbitrary and irrational manner and he has further pointed out that the two bulk drugs viz.

Mefenamic Acid and Amikacin Sulphate were wrongly deleted from the DPCO 1995 whereas the said drug Ciprofloxacin was erroneously

included in the DPCO 1995. He has pointed out that the sales turnover of Mefenamic Acid between the 1988-1992 was over Rs. 400 lakhs per

year. Similarly, the import value of Amikacin Sulphate in the year 1989-1990 was Rs. 350 lakhs which rose to Rs. 475 lakhs in the year 1990-

1991 and touched a level of Rs. 845 lakhs in the year 1992-1993. Mr. Chagla therefore pointed out that there are two formulators of these drugs

in the market and a single formulator has a market share in excess of 40% of retail trade as per ORG figures. Apparently, the Respondents had

originally included these two drugs in the DPCO 1995, whereas erroneously, arbitrarily and in an irrational manner excluded these two drugs from

the DPCO, 1995. Mr. Chagla has contended that the Respondents have adopted a ""pick and choose"" method, which clearly discloses the hostile

discrimination, subjectivity and a lack of transparency. Therefore, the learned counsel Mr. Chagla has contended that the Respondents action of

including the bulk drug Ciprofloxacin within the DPCO 1995 would be violative of Article 14 of the Constitution of India. In this Writ Petition

Respondents have filed an affidavit in reply but there are only bald denials, and no specific particulars and details are given to controvert the

contentions of the petitioners. Hence we find substance in the contention of Mr. Chagla that the Respondents have acted arbitrarily and in an

irrational manner in bringing the aforesaid drug Ciprofloxacin within the price control. Whereas, the Respondents have wrongly excluded the

aforesaid Mefenamic Acid and Amikacin Sulphate from the price control.

89. In Writ Petition No. 3031 of 1996 the bulk drug involved is Doxycycline and in Writ Petition No. 5219 of 1996 the bulk drug involved is

Glipizide. As far as drug Doxycycline is concerned, the learned counsel for the petitioner has pointed out that as per ORG data as on 31st March,

1990 the annual turnover of the said drug was only Rs. 316 lakhs and also at the relevant time there were at least 19 formulators and none of the

formulators had more than 40% market share in the retail trade as per ORG figures. The learned counsel has pointed out that as per the ORG data

there was no bulk drug producer with regard to the drug Doxycycline in the Country. The only company was Ranbaxy which was the manufacturer

of the drug Doxycycline but it captively consumed the same, and all the other formulators of Doxycycline had to depend on the imported bulk drug

Doxycycline. Mr. Kapadia, the learned counsel has pointed out that as far as the drug Doxycycline is concerned, there were at least 34

formulators and none of them were having more than 40% market share in the retail trade. So far as these two Writ Petitions are concerned, the

Respondents have filed an affidavit in reply but there are only bald denials, and no specific particulars and details are given to controvert the

contentions of the petitioners. Hence, we hold that the drug Doxycyline could not have been brought within the purview of price control.

90. As far as the other drug Glipizide is concerned, at the relevant time as on 31st March, 1990, the annual turnover of the said drug was Rs. 82

lakhs and even assuming that the petitioners were to be the sole manufacturers of the said drug as the turnover was below Rs. 100 lakhs, the

monopoly situation as envisaged in para 22.7.2(ii) of Drug Policy, 1994 does not apply and as such, the said drug Glipizide ought to be kept out of

the purview of DPCO 1995. Mr. Kapadia, the learned counsel has also pointed out that when the above petition No. 5219 of 1996 was filed in

this Court, an application for urgent relief was made on 18th October, 1996 as the petitioners had apprehended that the Government might be

fixing the price for the said drug Glipizide. The learned counsel appearing on behalf of the Respondents had assured the Court that the

apprehensions of the petitioners were unfounded as there was no decision taken to fix the price. Accordingly, the ad-interim relief was refused.

However, the learned counsel for the petitioner has pointed out that on 22nd October, 1996, the petitioners came to know that on 18th October,

1996 itself the Government had fixed the price in respect of the drug Glipizide which fact was not disclosed to the Court at the time when the ad-

interim application was made.

91. As far as the drug Glipizide is concerned, the learned counsel Mr. Kapadia has pointed out that the another drug known as Glibenclamide

which was initially included in the DPCO 1987 was subsequently excluded under DPCO 1987 and continued to remain excluded from DPCO

1995. The learned counsel Mr. Kapadia has pointed out that the another anti-diabetic drug included in DPCO 1995 was Insulin whereas

subsequently the same was excluded from the drug price control. The learned counsel Mr. Kapadia has pointed out that as per the ORG data the

annual turnover of the Insulin was Rs. 441 lakhs as on 31st March, 1990 and as such, it was rightly included in DPCO 1995, whereas the same

was wrongly excluded from the price control. On the contrary, the learned Counsel for the petitioner states that the Respondents have in an

arbitrary and mala fide manner have included the drug Glipizide which had only an annual turnover of Rs. 82 lakhs. Therefore the contention of the

learned counsel for the petitioner is that though all the aforesaid drugs are anti-diabetic drugs, the some of which ought to have been included but

have been excluded and, whereas, some of which ought to have been excluded but have been included, therefore, there is a hostile discrimination

violative of Article 14 of the Constitution of India. Under these circumstances, we hold that both the drugs; Doxycycline as well as Glipizide could

not have been brought within the purview of price control.

92. We therefore hold that the concerned drugs mentioned in respective petitions, do not fall within the purview of DPCO 1995 and as a

consequence, no fixation of price could be adopted with regard to the said drugs mentioned in the aforesaid Writ Petitions. As a consequence all

impugned notices demanding ""over charged amount"" from the petitioners are also quashed and set-aside. Rule is accordingly made absolute with

costs in all the above petitions including Writ Petition No. 1749 of 1999 as far as the issue regarding inclusion of the drugs concerned therein within

the purview of DPCO 1995 and on other issues the petition is kept open to be decided on merits. In view of the quashing of notices demanding

over charged amount"" nothing further survives in Contempt Petition No. 96 of 2000.

93. Personal Assistant to issue an ordinary copy of the order to the parties. Parties to act on an ordinary copy of this order duly authenticated by

the Associate of this Court.

94. Issuance of certified copy is expedited.