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(2000) 12 DEL CK 0024

In the Delhi High Court

Case No : Civil Writ Patition No. 2822 of 2000

M/s. E. Merck (India) Ltd. and another — APPELLANT

Vs

Union of India and another — RESPONDENT

Date of Decision : 21-12-2000

Acts Referred:
Constitution of India, 1950 — Article 14, 19, 226, 32

Citation : (2001) 2 AD 270 : AIR 2001 Delhi 326 : (2001) 90 DLT 60 : (2001) 57 DRJ 430

Hon'ble Judges : Arun Kumar, J;A.K. Sikri, J

Bench : Division Bench

Advocate : Mr. Anil B. Diwan, with Mr. Pramod B. Agarwala with Ms. Praveena Gautam and Mr. Sanjeev Kumar, for the Appellant; Mr. Maninder Singh with Mr. Nishikant Pandey, for the Respondent

Judgement

Arun Kumar, J.—By impugned Notification dated 14th October, 1999 the Central Government has in exercise of powers contained u/s 26A of the Drugs and Cosmetics Act, 1940 (as amended 68 of 1982) (hereinafter referred to as the Act, for short) prohibited manufacture, sale or distribution of Fixed Dose Combination (hereinafter referred to as FDC, for short) of Vitamins B1, B6 and B12 for human use w.e.f. 1st January, 2001. Petitioner is a pharmaceutical Company. Apart from manufacturing other medicines, it is the manufacturer of FDC of Vitamins B1, B6 and B12 which is marketed by it in the name of ''Neurobion'' in tablet and ingestible forms. Petitioners claim to have largest market share of this drug, with total sale of Rs.35.43 crores per year which is equivalent to approximately 23.6% of the total pharmaceutical products. It was, Therefore, but natural for the petitioners to feel aggrieved against this Notification and by means of present Writ Petition the petitioners had challenged the validity of this Notification. Challenge is also to the virus of Section 26A of the Act under which the aforesaid Notification is issued.

2. The exercise undertaken by the Central Government which culminated in the

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issuances of impugned Notification dated 14th October, 1999 has its origin in a Writ Petition filed in the Supreme Court under Article 32 of the Constitution of India being Civil Writ Petition No. 698 of 1993. This Writ Petition entitled Drug Action Forum versus Union of India and others was filed by the Drug Action Forum (hereinafter referred to as the Forum, for short) and is in the nature of Public Interest Litigation. In the said Writ Petition the Forum has averred that there are many drugs in the market which are hazardous or have no therapeutic value and sought direction to ban these drugs. Since the proceedings in the Supreme Court in the aforesaid Writ Petition have bearing on the present case, it would be necessary to take stock of such proceedings.

3. Petitioners herein moved an application in that Writ Petition before the Supreme Court for impleadment as a party as being vitally interested in the outcome of the Petition. This application for impleadment was allowed by Order dated 17th October, 1994 and petitioners have been participating in those proceedings ever since. Respondents herein filed affidavits from time to time pursuant to various Orders passed by the Supreme Court in that Writ Petition giving their views/comments as well as available material on various drugs including on FDC of Vitamin B1, B6 and B12. It may be mentioned that the Forum in the said Writ Petition had filed additional affidavit dated 5th May, 1994 covering various drugs and following averments were made in respect of FDC of Vitamins B1, B6 and B12:-

"Probably no other combination of drugs is an completely without rationale as combinations of Vitamins B1 (Thiamine), B6(pyridoxine) and B12(cyanocobalamine). Both Vit.B1 and B12 have specific indications related to their deficiencies. Why they should be combined along with Vit. B6 is anybody''s guess. This combination does not find mention any standard work of Medicine and Pharmacology. Yet a large number of these combinations as injections or tablets are propagated. They are propagated as general "Health Tonics" and for a large variety of obscure to common neurological problems."

"Vitamin B12 has an undeserved reputation as a health tonic and has been used for a number of diverse disease states .....

Therapy should always be as specific as possible. While a large number of multi-vitamin preparations are available, the use of "shotgun" therapy in the treatment of Vitamin B12 deficiency can be dangerous..."

GOODMAN and GILMAN''s the Pharmacological Basis of Therapeutics, Seventh Edition (1986).

"Adverse reactions virtually do not occur, but its use as a "tonic" is an abuse of a powerful remedy for it may obscure diagnosis of pernicious anemia which is a matter of great importance in a disease requiring lifelong therapy, and prone to serious neurological complications".

CLINICAL PHARMACOLOGY, D.R. Laurance and P.N.Bannett, Fifth Edition (1980).

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All combinations of Vitamins B1, B6 and B12 should be banned immediately.

4. The Government filed its reply to this additional affidavit and the initial reaction in the said affidavit was that FDC of Vitamins B1, B6 and B12 (hereinafter referred to as the banned Drug, for short) with permitted minimum and maximum quantities could be administered and the product was permitted in various countries. Record shows that Supreme Court in the aforementioned Writ Petition had passed Order dated 17th November, 1994 directing the Drug Technical Advisory Board (hereinafter referred to as the DTAB, for short) to obtain fresh report on reassessment of the quality and nature of the drugs specified in the Petition and for other drugs which may be specified on behalf of the Forum from the DTAB constituted u/s 5 of the Act, to enable the Court to deal appropriately with the questions raised in the Petition. The DTAB was permitted to constitute a technical sub-Committee for the purpose of expediting its work and it was specifically directed that in this Sub-Committee Dr. Nitya Nand, Dr. N.H. Antia and Dr. Naresh Banerjee be included as Members. It was further directed that the DTAB should submits its report within three months and monthly interim reports be also filed in the meantime. Technical Sub-Committee was constituted which held sittings from time to time. Its Minutes dated 27th January, 1995, 15th February, 1995 and 16th February, 1995 show that as far as this drug is concerned, the Committee was of the opinion that more data be generated on the subject. On these Minutes Dr. Antia has given his comments inter alias making a point that all drug combinations not recommended by renowned Text Books or National Formularies be banned. Thereafter certain affidavits and Minutes of the special meetings held by DTAB were filed which reflected that as far as Dr. Antia and Dr. Naresh Banerjee are concerned they were of the view that FDC of Vitamins B1, B6 and B12 should be banned. They had examined the submissions made by drug companies also, but did not find any justification in the material provided by the drug companies to support their claim in favor of this banned Drug. It is further revealed from the Minutes of the special meetings of DTAB that it had decided that manufacturers of the banned Drug be asked to modify the package, necessary in promotional literature giving only restricted indication as approved by the experts and get it approved by the Drug Controller within a stipulated period of time. When the matter was being considered in this manner by the expert Sub-Committee, the Supreme Court passed Order dated 12th February, 1997 Constituting a Core Group including the coopted Members plus the Director General of Health Services, Director General of Armed Forces Health Services and the Drugs Controller General of India. Five out of the six Members who constituted the Core Group were Members of the DTAB which examined the FDC of the banned Drug Along with other drugs mentioned in the list furnished by the Forum to the Apex Court. The Supreme Court also specified in the Order that any material which is considered relevant by any of the affected parties may be communicated by their counsel to the Additional Solicitor General for onward transmission to the Convener of the Core Group for consideration by Core Group before formation of its opinion. In

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compliance of the aforesaid Order dated 12th February, 1997, respondents addressed letter dated 17th February, 1997 to the petitioners requesting them to make available any material to be considered by the Core Group. This material was submitted by the petitioners and the same was handed over to the Members of the Core Group for their consideration.

5. The Core Group thereafter went ahead with its task. Its deliberations are amplified in the additional affidavit dated 4th December, 2000 filed by the respondents in this Writ Petition. A perusal thereof shows that the Chairman of the Core Group during one of its deliberations held on 26th February, 1997 had sought guidance from the members whether it would be appropriate to deliberate on the issues right at the meeting or members would like to go through the documentation and fix a future date for deliberation on the subject. Chairman of the Core Group also stated that any other technical literature quoted by expert members will also be referred to while discussing the issue. The Core Group after an elaborate and detailed examination of the materials made available by the petitioners as well as standard text books reference available on the subject found the FDC of the banned Drug had no rationality in the specific conditions for which it is being marketed and do not have any superiority over the individual vitamins which could be administered in desired therapeutic doses to treat the specific deficiencies.

6. The report of the Core Group was submitted to Supreme Court in the Petition filed by the Forum on 7th May, 1997 and the relevant portion of this reads as under:-

"The marketing of Fixed Dose Combination or Vit B1, B6 and B12 was discussed in detail. The Core Group was of the opinion that while there is no rationality of this combination in large number of cases, it might have very limited role in a few medical conditions. It was strongly felt that there is inappropriate use of such combinations in the form of tablets and injections. The Core Group recommended that to begin with, the drug should be phased out from the general market in first 12 months from the date of notification and allow its use thereafter only in the hospitals as an ingestible for another 12 months. However, after the period of 24 months it should be withdrawn from the Indian Market. The above recommendation should be placed before DTAB for its consideration.

7. Respondents produced the records during the course of hearing. The record shows that the DTAB in its 47th Meeting held on October 27, 1998 discussed the report of the Core Group and agreed with its recommendations that such FDCs should be phased out from the market because of their improper use and lacking rationality. The Board also recommended that FDC of the banned Drug should be prohibited from January 1, 2001. The matter was thereafter referred to the Government for taking a view in the matter. Noting in the relevant file further shows that it was mentioned that for taking a view in the matter two issues needed to be looked into:- (a) Whether FDC are merely irrational or harmful to health and (b) if the ingestible has limited use, what is the logic of giving an

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extension for its phasing out only for additional year and how will these ingestibles be replaced within that additional time given ? The matter was thereafter considered keeping in view the aforesaid two issues as well. The record shows that the reasons for giving two years period for phasing out, deliberated in meeting of experts/DTAB was to have a common cut off period for all formulation (oral and ingestible) and allow adequate familiarizations or shift over period to practitioners who are routinely prescribing this DC. After the government was satisfied that the manufacturer, distribution and sale of the banned Drug needs to be prohibited and decision to this affect having been taken at the highest level, the impugned Notification dated 14th October, 1999 was issued.

8. The challenge of the petitioner to the aforesaid. Notification as well as virus of Section 26A of the Act is couched in the following manner :-

1. Section 26A is ultra virus the Constitution. For it:

a. does not provide for any hearing;

b. does not provide for any appeal;

c. confers in Central Government unfettered, unrestricted power to prohibit sale, distribution or manufacture of a drug;

d. does not provide for any Rules/Regulations as to how satisfaction has to be arrived at;

e. does not provide for furnishing of any reason for prohibiting sale, distribution or manufacture of a drug except bald statement to the effect that Central Government is satisfied ...''.

It was accordingly submitted that Section 26A of the Act confers uncontrolled and unguided power on the Government and Therefore it was unsustainable being vocative of Article 14 and 19 of the Constitution of India and the judgment of the Supreme Court in the case of B.B. Rajvanshi versus State of U.P. reported in 1998 (2) SCC 415 was cited in support of this argument.

2. It was contended that a Notification directing ban on a drug leads to civil consequences and as such right to fair and purposeful hearing is built in. But the petitioners were not given any proper/fair or purposeful hearing before prohibiting the drug. It was submitted that hearing is not an empty public relation exercise and must be genuine i.e. party must know the case it has to meet and it should be given an opportunity to meet it. The order to prohibit the drug has been passed in undue haste. There was no reason for the Central Government not to give fair and proper hearing to the petitioners especially when the drug was under consideration since 1994-95, was allegedly recommended to be banned in meeting dated 18th March, 1997 and notification to ban the same was issued on 14th October, 1999 prohibiting the manufacture, sale or distribution of FDC w.e.f. 1st January, 2001. Consequently, there was no

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reason why a proper hearing could not have been granted to the petitioners before issuing the impugned Notification. Alleged opportunity to furnish any material that the petitioners would like to place before the Core Group for consideration vide letter dated 17th February, 1997 was at the best investigative in nature to collect the material for forming a prima facie view. However, it was imperative for the Core Group to give a fair hearing to the petitioners to place their case and view points if prima-facie material was found against the drug to explain the said material. Consequently, the alleged opportunity is an eye wash and does not amount to hearing as contemplated in law.

Learned counsel in contending that the principles of natural justice had not been followed while passing impugned Notification and Therefore the Notification was bad in law, relied upon the following judgments : C.B. Gautam Vs. Union of India and Others, in support of the submission that Courts generally read into the provisions of the relevant sections, the requirement of giving a reasonable opportunity of being heard before an order is made which would have adverse civil consequences for the parties affected. It was submitted that the provisions of Section 26A of the Act could be saved only if requirement of giving a reasonable opportunity of being heard is read into it. Reliance was placed on the Division Bench judgment of this Court in the case of M.N. Gupta and Another Vs. University of Delhi and Others, ; Jagroop Singh Gill and others Vs. State of Punjab and others, , Mahender Singh Gill versus Chief Election Commissioner reported in AIR 1978 SC 581, Swadeshi Cotton Mills Vs. Union of India (UOI), .

3. It was also submitted that even if it was assumed that the Act provides for procedure for evaluation of the drugs, the records produced do not disclose that such procedure was followed i.e. no material relating to the findings of the Core Group were placed before DTAB for consideration; no material showing that findings arrived at by the Core Group was considered by DTAB or by the Central Government for its decision and no material was placed showing that the Central Government considered the report of the DTAB or Drug Consultative Committee while arriving at its satisfaction. A decision without following any principle or rule is unpredictable and antithesis of a decision in accordance with rule and law. It was the contention of the petitioners that nothing is placed by the Government to show any material in support of banning the drug. On the contrary, there was sufficient material to show that the drug has therapeutic value.

Referring the various affidavits and reports filed before the Supreme Court in the aforesaid Petition filed by the Forum, learned counsel for the petitioners also made an attempt to show that no material was available to support the ban of the drug in question. On the other hand, there was sufficient material on record which disclose that the drug had therapeutic value. Reference was made to pleadings in the Writ Petition and to some of the documents annexed thereto to justify this stand. On this basis, it was sought to argue that the formation of the opinion by the Central Government was without any supporting material and Therefore the requirement of Section 26A indicating ''satisfaction'' of the Central

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Government were not fulfilled. Such a decision, it was submitted, was clearly unsustainable and could be judicially reviewed. For this proposition, reliance was placed on The Barium Chemicals Ltd. and Another Vs. The Company Law Board and Others, , Rohtas Industries Vs. S.D. Agarwal and Others, .

4. It was further submitted that the entire record produced by the respondents shows that the reason to prohibit the sale, distribution or manufacture of the drug is personal bias of the two of the members of the Core Group i.e. Dr. Antia and Dr. Banerjee who took wholly unreasonable stand that all drug combinations not recommended by the text books or national formularies be banned. Such a decision, it was argued, lacked in fairness and was arbitrary and thus vitiated in view of the principles laid down by the Supreme Court in the case of Tata Cellular Vs. Union of India, .

5. It was submitted that the drug is not hazardous to health and is manufactured in India, Europe, USA and many other developed countries for last over 3 to 4 decades. In case a drug which is widely used all over the world has to be prohibited, there has to be much stronger reason to prohibit the sale, distribution and marketing of the said drug and not that the said two experts could not find rationale of said drug either in text books or national formularies. It was also submitted that before the drug is banned u/s 26A of the Act it is necessary to show that either the drug was dangerous to human life or that it did not have therapeutic value or that public interest required prohibition of its manufacture, sale or distribution. This was not shown by the respondents and Therefore the decision of the Government was unsustainable and needed to be quashed. For this purpose, learned counsel heavily relied upon judgment of Calcutta High Court in the case of West Bengal Small Scale Pharmaceuticals Manufacturers Association versus Union of India reported in AIR 1977 Cal 186 and that of the Bombay High Court in the case of Unichem Laboratories Ltd. and Another Vs. Union of India (UOI), .

6. Lastly, it was argued that the impugned Notification gives the reason for prohibiting the sale, marketing and distribution of the drug as the same has non therapeutic value as claimed. However, in the counter affidavit, the reason disclosed for its ban is "inappropriate use of the drug" and in this eventuality it was argued, that the Notification cannot stand because the same is supported by reason which are outside the reasons furnished in the Notification and the proper course to stop improper use of the drug is not to prohibit the sale, manufacture, distribution of the drug but to make it strictly a prescription drug. It was submitted that the respondent could support the impugned Notification on the basis of reasons given therein and not by any other reason as held in the case of Mahender Singh Gill (supra).

Mr. Maninder Singh, learned counsel appearing on behalf of the respondents attacked the very edifice of the petitioners case. His submission was that any Notification u/s 26A of the Act is an act of subordinate legislation inasmuch as every notification under this provision is of general application. In other words,

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the exercise of power u/s 26A of the Act is not an administrative power but a legislative power. In order to demonstrate that any Notification passed in exercise of powers u/s 26A of the Act would amount to legislative function, his submission was that the Notification passed u/s 26A would have universal/ general application and such a Notification would be legislative in nature. For this purpose he relied upon the following observations of the Supreme Court in the case of Union of India (UOI) and Another Vs. Cynamide India Ltd. and Another etc., :-

"The third observation we wish to make is, price fixation is more in the nature of a legislative activity than any other. It is true that, with the proliferation of delegated legislation, there is a tendency for the line between legislation and administration to vanish into an illusion. Administrative, quasi-judicial decisions tend to merge in legislative activity and, conversely, legislative activity tends to fade into and present an appearance of an administrative or quasi-judicial activity. Any attempt to draw a distinct line between legislative and administrative functions, it has been said, is difficult in theory and impossible in practice''. Though difficult, it is necessary that the line must sometimes be drawn as different legal rights and consequences may ensue. The distinction between the two has usually been expressed as ''one between the general and the particular''. ''A legislative act is the creation and promulgation of a general rule of conduct without reference to particular cases an administrative act is the making and issue of a specific direction or the application of a general rule to a particular case in accordance with the requirements of policy''. ''Legislation is the process of formulating a general rule of conduct without reference to particular cases and usually operating in future; administration is the process of performing particular acts, of issuing particular orders or of making decisions which apply general rules to particular cases''.

9. It was further submitted that in fact Section 26A of the Act which confers power on the Central Government to issue Notification was in the nature of public duty cast upon the Government before discharging the function of banning a particular drug, once it was satisfied that ingredients mentioned in Section 26A are present. Thus Section 26A of the Act casts a duty on the Central Government to ensure that no such drug is prevalent in the market which comes within the mischief of parameters mentioned in this Section.

10. It was argued that once it is accepted that power u/s 26A of the Act was legislative in nature the legal complexion changes altogether. Different legal principles would apply. Then unless and until the statutory provision providing for subordinate legislation, itself incorporates a mechanism for notice and hearing, etc., principles of natural justice are excluded while exercising a legislative power. The Provisions of Section 26A26A of the Act do not provide for any notice and/or hearing and as such all the arguments to the contrary on behalf of the petitioners are not sustainable. For this proposition reliance was placed on para 5 of the judgment in the case of Cynamide India Ltd (supra) which reads as under:-

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"The second observation we wish to make is, legislative action, plenary or subordinate, is not subject to rules of natural justice. In the case of Parliamentary legislation, the proposition is self-evident. In the case of subordinate legislation, it may happen that Parliament may itself provide for a notice and for a hearing (sic) there are several instances of the legislature requiring the subordinate legislating authority to give public notice and a public hearing before say, for example, levying a municipal rate - in which case the substantial non-observance of the statutorily prescribed mode of observing natural justice may have the effect of invalidating the subordinate legislation. The right here given to rate payers or others is in the nature of a concession which is not to detract from the character of the activity as legislative and not quasi-judicial. But,where the legislature has not chosen to provide for any notice or hearing, no one can insist upon it and it will not be permissible to read natural justice into such legislative activity."

11. Another fall out of the legislative character of the Notification u/s 26A of the Act, it was submitted, is that the presumption of constitutionality was in favor of such legislation which was settled law laid down in the series of judgments of the Apex Court. Reference was made to the following cases : B. Banerjee versus Anita Pan reported in 1975 (1) SCC 167; R.K. Garg and Others Vs. Union of India (UOI) and Others, ; Supreme Court Employees'' Welfare Association versus Union of India and another ; Dalmia Cement (Bharat) Ltd. and Another Vs. Union of India (UOI) and Others, .

12. It was also submitted, in the same vein, that burden to prove the unconstitutionality was upon the petitioners who were challenging the Notification and petitioners had not been able to discharge this burden. Further, according to the learned counsel for the respondents, the entire thrust of the petitioner''s arguments shifting the onus on the Government to prove that the impugned Notification was valid was contrary to the well settled position in law.

13. Justifying the issuance of the impugned Notification dated 14th October, 1999 it was submitted that the ''satisfaction'' arrived at by the Government u/s 26A of the Act in issuing the impugned Notification dated 14th October, 1999 is bonafide and is based on the conclusion in the Report of the expert Committee appointed by the Supreme Court and on due consideration thereof by the DTAB. It was also submitted that there is no rationality or justification in continuing the FDC of the banned Drug. It was further submitted that for all the indications and/ or diseases where any of the above mentioned Chemicals are needed, they would be individually and separately available and as such, there is not going to be any vacuum or non-availability of any required medicine/drug. Admittedly vitamins B1, B6 and B12 contain Chemicals and if human body only requires either one or two kinds of these vitamins, there is no justification in giving all the three together and administer unnecessary Chemicals. Therefore, the decision of the Government in issuing the impugned Notification dated 14th October, 1999 is absolutely logical and rational. Learned counsel further submitted that it is a

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settled position in law that when the Government takes a decision on the basis of the recommendation of the experts of the field, even if another view is possible, the courts would not interfere with the decision while exercising jurisdiction under Article 226 of the Constitution of India.

14. Learned counsel for the petitioners, challenged the stand of the respondents contending that the Notification issued u/s 26A of the Act was not legislative action. It was submitted that it was an administrative act. He further submitted that the case of Cynamide India Limited (supra) has no application inasmuch as the observations made by the Supreme Court in that case were made while dealing with the price fixation under the Essential Commodities Act. Learned counsel for the petitioners argued that a bare reading of Section 26A of the Act discloses that the powers conferred on the Central Government is of general nature and is for controlling the prices at which any essential commodity may be bought or sold. It provides for prohibition of any drug which doe snot have therapeutic value claimed or purported to be claimed. The word ''any drug'' itself refers to a particular drug. A particular drug in turn refers to a particular person who manufactures the said drug or, group of persons which manufacture particular drug. In addition Government has to be satisfied that ingredients u/s 26A do exist. Such satisfaction has to be objective and relevant material must exist before the Government can issue notification. Consequently, to arrive at such satisfaction there has to be cogent material. In other words the exercise of powers depending on the existence of circumstances to be so determined is an administrative action. The Notification issued under the Act is not of general application but applies to specific medicine manufactured by specific manufacturers. He further submitted that the Notification issued results in civil consequences on the manufacturers. Bombay High Court and Calcutta High Court have read the Notification issued u/s 26A of the Act as administrative action and have also emphasized on right of hearing to the manufacturers. Supreme Court also in the case of Systopic Laboratiries (Pvt.) Ltd. Vs. Dr. Prem Gupta and others, declined to interfere with the orders passed by the Central Government because adequate hearing was given to the manufacturers and affected parties. In the case of State of T.N. represented by Secretary, Housing Deptt., Madras Vs. K. Sabanayagam and Another, , it was held "but where he merely determines either subjectively or objectively depending on the "conditions" imposed in the statute permitted exercise of power by the delegate - there is no legislation involved in the real sense and, Therefore, in our opinion, applicability of principles of fair play, consultative or natural justice to the extent necessary cannot be said to be foreclosed....."

15. Learned counsel also referred to the averments made in the counter affidavit of the respondents themselves as per which exercise was undertaken by various committees in order to arrive at the conclusion as to whether the drug in question should be banned or not and this clearly showed that it was an administrative action. Concluding his submission an alternate plea was made that in case this Court comes to the conclusion that prohibition imposed by the

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Government is justified, in the said eventuality and in view of the fact that the drug in question is under manufacture, is in the market and, stocks of raw material have been purchased which would need to be consumed otherwise the same would be spoiled, it is just and necessary that the petitioners be granted about 16 weeks time to consume the existing raw material, stop the manufacture and marketing of the drug and to take suitable steps to withdraw the drug from the market inasmuch as u/s 28 of the Act contravention of the order is punishable with imprisonment.

16. We have given out thoughtful consideration to the various contentions advanced by both the parties and have also perused the pleadings supported by documents as well as records produced by the respondents.

17. In so far as the challenge to virus of Section 26A of the Act is concerned, we are not impressed. There is hardly any basis for the contention that Section 26A of the Act is unconstitutional or vocative of Articles 14 and 19 of the Constitution of India. The Act was passed in the year 1940 with the purpose to regulate the import, manufacture, distribution and sale of drugs and cosmetics. By the Amendment Act 68 of 1982 apart from other provisions, Section 26A was incorporated by way of amendment to this Act. The purpose behind introduction of such a provision is obvious. Central Government is empowered, by the Parliament, to prohibit the manufacture, sale or distribution of a drug or cosmetic. Before imposition of such ban following ingredients as contained in Section 26A of the Act are to be fulfilled : (i) Satisfaction of the Central Government; (ii) Satisfaction has to relate to :- (a) likely to involve risk to humans and animals, or (b) it does not have a therapeutic value as claimed or purported to be claimed for it; or (c) it contains ingredients and in such quantity for which there is no therapeutic justification; (iii) it is necessary or expedient in public interest to do so.

18. The intention of the legislature is that the drugs which are hazardous or without therapeutic value or without any therapeutic justification should not be allowed to be manufactured, sold or distributed. The provision made has laudable objective and it is clearly a reasonable restriction on the freedom of carrying business by any person. In fact in Cynamide India case (supra) challenge to virus of Section 26A of the Act was repelled by Supreme Court. Further, the ingredients mentioned above clearly spell out that the power given to the Central Government is neither uncontrolled nor unguided. A particular drug would be banned only if the Government is satisfied about the hazardous nature of the drug or its nil therapeutic value, or no therapeutic justification. Above all, the Government is also to be satisfied that public interest warrants such prohibition. All these factors constitute definite guide-lines to the Central Government before it acts to issue the Notification u/s 26A of the Act prohibiting manufacture, sale or distribution of a drug or cosmetic and Therefore removes the element of arbitrariness.

19. For such a provision to sustain it is not necessary that statutory appeal has

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to be provided. Even in the absence of statutory appeal the aggrieved person has the constitutional remedy of challenging the Notification by filing Writ Petition under Article 226 to the High Court or under Article 32 to the Supreme Court. The Scheme of the Act further provides for constitution of Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee for the purpose of carrying out the functions assigned to it by the Act. Before the Government records its satisfaction to prohibit the manufacture, sale, distribution etc. of a particular drug, opinion of the DTAB and/or Drugs Consultative Committee is obtained. Whenever decision of the Central Government taken u/s 26A of the Act is challenged, while exercising the power of judicial review of such a decision the Court can go into the question as to whether the satisfaction was based on material, which was relevant and germane to the issue and that it was not an arbitrary exercise of power. Thus, we hold that provision of Section 26A are not ultra virus the Constitution of India.

20. In so far as other argument of the petitioners are concerned, the type of glance or legal consideration they require would depend on the question as to whether the power exercised u/s 26A of the Act is legislative in nature or it is an administrative function being discharged by the Central Government. We may say that there appears to be force in the submission of the respondents that the power is legislative in nature keeping in view the principles laid down by the Supreme Court in Cynamide India Limited. (supra). However, it is not necessary to examine this question in detail in the instant Petition inasmuch as even if it is treated to be administrative in its flavour, on the facts of this case we have no hesitation to come to the conclusion that the exercise of power u/s 26A of the Act by issuing the impugned Notification dated 14th October, 1999 is valid and the impugned Notification does not suffer from any infirmity.

21. In so far as argument of non-grant of fair and purposeful hearing is concerned, we do not agree with the petitioners that they did not have opportunity to present their point of view. One cannot lose sight of the fact that the exercise undertaken by the respondents was pursuant to the direction issued from time to time by the Supreme Court in the Writ Petition filed by the Forum. It has already been noted above that as far back as on 17th November, 1994 Supreme Court had passed the Order directing DTAB to go into the question relating to the drugs mentioned in the Petition filed by the Forum and submit its report in relation to these drugs. For this purpose, DTAB was permitted to constitute a technical Sub-Committee and the Supreme Court directed that members of this Sub-Committee would include Dr. Nitya Nand, Dr. N.H. Antia and Dr. Naresh Banerjee. Petitioners are also imp leaded as party in the said Writ Petition pending in the Supreme Court and have been participating in the hearings. Petitioners, as per their own admission, submitted the material and data in their possession in support of continuation of FDC of banned Drug which was duly considered by the Sub-Committee. Not only this, by Order dated 12th February, 1997, while Constituting the Core Group, Supreme Court specifically gave an opportunity to the petitioners and other affected parties to supply any

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material which they considered relevant to Additional Solicitor General of India for being transmitted to the Convener of the Core Group for its consideration before the formation of its opinion. It is also an admitted position that the petitioners in fact submitted the material in support of its case which was duly considered by the Core Group. Thus, not only, the view point of petitioners were considered, the respondents in fact acted in the manner directed by the Supreme Court from time to time. This, according to us, would be sufficient compliance of the principles of natural justice. The sequence of events further demonstrate that the petitioners had been given reasonable opportunity to project their point of view. Thus the Order does not suffer from the vice of non grant of reasonable opportunity of being heard. While the principles laid down in various judgments quoted by the petitioners cannot be disputed, suffice would be to state that in the present case there is a compliance with such principle and opinion of the judgments quoted by the petitioners does not advance their case. We do not agree with the contention of the petitioners that the Government was under obligation to issue show cause notice before issuance of impugned notification. It may also be relevant to point out at this stage that in Systopic Laboratories (supra) case which related to Notification issued u/s 26A of the Act itself, the Supreme Court while upholding the said Notification felt satisfied that the material placed by the appellants in the said case was duly considered by the DTAB or Drug Consultative Committee.

22. There is also no merit it in the contention that the impugned Notification was passed without any material on record. As already pointed out above, voluminous material was placed before the Sub Committee in the first instance. The Core Group also considered this material including the material furnished by the petitioners. After considering this material the Core Group opined that the drug in question should be banned. Affidavit to this effect Along with report of the Core Group was even filed before the Supreme Court in the Petition filed by the Forum. The material is also available in the form of opinions of Dr. Antia and Dr. Naresh Banerjee who were inducted as Members of the Core Group by specific Orders of the Supreme Court. Going by the deliberations of the Core Group, thereafter by the DTAB accepting the recommendation of the Core Group and independent look into the matter by the Central Government before issuing the Notification clearly shows due and proper application of mind. The relevant material is placed on record Along with the counter affidavit and as well as the original record shown to us at the time of arguments fully demonstrates this.

23. The arguments of the petitioners that the entire basis of the decision is the opinion of two Members of the Core Group namely, Dr. Antia and Dr. Naresh Banerjee who had personal bias is also without any merit. It is totally untenable on the part of the petitioners to argue that the decision lacks fairness or is arbitrary. u/s 26A of the Act, manufacture of a drug can be banned if the Central Government is satisfied that the drug does not have any therapeutic value. It can also be banned if the Central Government is satisfied that it does not have therapeutic justification. If a particular FDC has no therapeutic justification it

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would be in public interest to prohibit the manufacture, sale or distribution of such a drug. One has to keep in mind the ground realities prevailing in a poor country like India. If the drug in question did not have any therapeutic justification and doctors prescribe this drug as a matter of routine, it would be unnecessary and unjust burden on the pockets of poor people in this country to have such a drug. It was rightly argued by the respondents that with the change in times, now the emphasis is on therapeutic rationality for continuing the drug i.e. whether a drug is really required at all. If it does not have any rationale or therapeutic justification that would also be one of the relevant factors mentioned in Section 26A of the Act which may permit the Central Government to issue Notification prohibiting the manufacture etc. such a drug. Therefore, it is not necessary that a drug has to be only hazardous before it is banned. It is also not necessary that sufficient material is not available to show that a particular drug lacks therapeutic value. Once it is found that the drug in question lacks therapeutic justification that would be sufficient for the satisfaction of the Central Government u/s 26A of the Act. It is not disputed that Vitamins B1, B6 and B12 are available separately. It is not a case of the respondents that these vitamins taken individually do not have therapeutic value. What is prohibited by the impugned Notification is the fixed dose combination of the three vitamins. If a patient/person requires either vitamin B1 or B6 or B12, what is the justification in giving him vitamin B-Complex which contains fixed dose combination of vitamins B1, B6 and B12 thereby administering other two vitamins not needed. After all these tablets or injections or vitamins contain Chemicals and unnecessary Chemicals are being administered by giving FDC of banned Drug which are not required. Therefore, when the opinion of Dr. Antia or Dr. Naresh Banerjee suggested that FDC does not have therapeutic value/justification and there was no material available in the Text Books or National Formularies to support it, that would also be a relevant consideration. In any case the Core Group had discussed the entire matter before accepting such opinion and did not blindly follow the opinion of these doctors. Same exercise was done by DTAB and thereafter by the Central Government. Therefore, the argument that Notification was result of personal bias of two doctors, cannot be accepted.

24. Once we come to the conclusion that the ingredients of Section 26A of the Act are fulfilled, that the satisfaction of the Central Government is based on material on record after considering all possible views in the matter and relevant material germane to the issue was considered and the action was not ultra virus the powers of the Central Government, no further scrutiny of the matter is required while exercising the power of judicial review over such a decision. After all this Court is not sitting in appeal against the decision of the respondents. Judicial review of such a decision is available on limited grounds. While on the one h (sic) and Court is not sitting on appeal over the decision making authority, it has to preserve democratic values of rule of law. From this angle Court is to ensure that the authority who has taken the decision acts within the bounds of law and its power. Over a period of time grounds have been evolved on which

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judicial review of administrative action is permissible. The administrative decision can be interfered with if it lacks in fairness or is mala fide, it is ultravires, or abuse of power or colourable exercise of power and passed for improper purpose or it is based on irrelevant considerations or relevant material is not taken into consideration. Once the court is satisfied that a particular decision taken was within the power of the authority and it is not an abuse of such power and has not been taken with improper motive and is based on relevant material, it is not within the purview of a Court to substitute its own decision over the decision of the appropriate authority as if sitting in appeal. Way back in the year 1964 this is what the Supreme Court had observed on this point in the case of S. Pratap Singh Vs. The State of Punjab, in the following words:

"The Court is not an appellate forum where the correctness of the order of the Government can be canvassed and, indeed, it has no jurisdiction to substitutions own view...for the entirety of the power, jurisdiction and discretion...is vested by law in the Government".

25. Similarly, in Asif Hameed and others Vs. State of Jammu and Kashmir and Others, , the Supreme Court enumerated the power of judicial review of administrative action in the following words (at page 1906):

"While exercising power of judicial review of administrative action, the Court is not an appellate authority. The Constitution does not permit the Court to direct or advise the executive in matters of policy or to sermonize qua any matter which under the Constitution lies within the sphere of legislature or executive, provided these authorities do not transgress their constitutional limits or statutory powers".

26. Thus judicial review is not an appeal from a decision but a review of the manner in which decision was made. The purpose of judicial review is to ensure that an individual receives fair treatment and not to ensure that the authority after according fair treatment, reaches on a matter which it is authorised or enjoined by law to decide for itself a conclusion which is correct in the eyes of the Court.

27. Even the power of judicial review is limited and circumscribed by the principles enumerated above. It is discernible that there was due application of mind on the part of respondents and their decision is based on relevant material on record which is manifest of the foundation on which the decision rests. This translucent and vitreous material coupled with the fact that under the Act it is the statutory function and power of the respondents to prohibit manufacture etc. of such a drug leaves no scope for further scrutiny or analysis of the matter. This Court is not supposed to adjudicate upon the correctness of the reports or the respective claims.

28. By now it is also well settled that the matters which are to be decided by experts, are to be left for them to decide and once such expert bodies take decisions in technical and scientific matters, it is not for the Court to interfere

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with the evaluation made by these expert bodies. In fact the argument which is advanced by the petitioners on the basis of the reports of DTAB and the arguments raised before Supreme Court and was considered by the Supreme Court in the case of Systopic Laboratories (Pvt.)Ltd. Vs. Dr.Prem Gupta and others (Supra) and other connected petitions reported in the said judgment. That was a case where validity of the notification issued by the Government of India prohibiting completely the manufacture and sale of fixed dose combination of cortoosteroids with any other drug for internal use was challenged. In the said notification it was stated that Central Government was satisfied that long term use of steroids in fixed dose combinations for treatment of asthma is likely to involve risk to human beings and such formulations do not have therapeutic justification and further that it was necessary and expedient in public interest to prohibit the manufacture and sale of the said drugs. On behalf of the petitioners, scientific data in the form of published papers in the various medical journals had been filed to show that fixed dose combination of a cortoosteroids and an antihistamine is highly beneficial for the treatment of asthma. Relying upon such studies, it was sought to be argued that the decision of the Central Government in prohibiting the manufacture and sale of the drug in question was not proper. While rejecting the contention of the petitioners, the Court observed as under:

"Having considered the submissions made by the learned counsel for the petitioners and the learned Additional Solicitor General in this regard, we must express our inability to make an assessment about the relative merits of the various studies and reports which have been placed before us. Such an evaluation is required to be done by the Central Government while exercising its powers u/s 26A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the Drugs Consultative Committee (DCC)".

29. The Court also brushed aside the argument of the petitioners that the material sought to be produced by the petitioners although submitted before the Sub-Committee of the Drugs Consultative Committee (DCC) as well as Expert Committee set up by it, there was no proper consideration of the same by the experts as well as the DCC and the Board. The Court, in the process, perused the minutes of the meeting of the Board, the sub-Committee of the DCC as well as Expert Committee which revealed that the material that was submitted on behalf of the manufacturers of the Drugs in question was examined by the members and, Therefore, it could not be held that there had been no proper consideration for the said material by the Expert Committee or the sub-Committee of the DCC. As already mentioned above, this exercise has been undertaken by the respondents in the instant case as well.

30. Even the arguments of the petitioners that the impugned Notification gives a different reason for prohibiting the manufacture, sale, distribution etc. of the drug than what is stated in the counter affidavit is without any basis. Nodoubt in para 1 of the Notification it is mentioned that FDC in question does not have

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therapeutic value, para 2 further stipulates that it is necessary and expedient to prohibit the manufacture, sale or distribution of the said combination in public interest. Further record produced by the respondents shows that one of the considerations for prohibiting the manufacture of the drug was that the reason for prohibition was inappropriate use and lack of rationality. Order is sought to be justified on the same ground which were mentioned in the impugned Notification and not on different grounds and that too with the aid of records.

31. The result of the aforesaid discussion is that the Writ Petition has no merit and deserves to be dismissed. The impugned Notification is validly made u/s 26A of the Act which is intra virus the Constitution.

32. Since the ban is coming into effect from January 1, 2001 and there is hardly any time left in between for the petitioners to consume the existing raw material, stop the manufacture and marketing of the banned Drug and take suitable steps to withdraw the drug from the market. We grant eight weeks time to the petitioners to consume the existing raw material and stop manufacture thereof subject to following conditions :-

A. The petitioners shall not purchase any fresh raw material for the purpose of manufacture of the banned Drug.

B. The petitioners would inform the respondents of the stocks of the existing raw material as well as of finished goods within seven days of passing of this Order.

C. The drug manufactured from the existing raw material and available stocks would not be marketed in India and would be only for export purposes to the countries where this drug is marketed.

D. If the petitioners are not able to export and phase out their stocks within eight weeks, the petitioners shall have to destroy the same.

33. Petitioners shall also file an affidavit of undertaking thereby agreeing to comply with the aforesaid conditions by 3rd January, 2001 in this Court with advance copy to the respondents. It is made clear that the aforesaid concession given to the petitioner is conditional and in case the affidavit by way of undertaking is not filed, this concession of granting eight weeks shall not become operative.

34. No costs.

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