Systopic Laboratories (Pvt.) Ltd vs Dr Prem Gupta.J.) on 22 September, 1993

Equivalent citations: 1994 AIR 205, 1994 SCC SUPL. (1) 160, AIR 1994 SUPREME COURT 205, 1993 AIR SCW 3645, (1993) 5 JT 391 (SC), 1994 (2) FAC 161, 1994 (1) SCC(SUPP) 160, (1993) 2 EFR 623, (1994) 2 FAC 161

Author: S.C. Agrawal

Bench: S.C. Agrawal

PETITIONER:
SYSTOPIC LABORATORIES (PVT.) LTD.

Vs.

RESPONDENT:
DR PREM GUPTA.J.)

DATE OF JUDGMENT22/09/1993

BENCH:
AGRAWAL, S.C. (J)
BENCH:
AGRAWAL, S.C. (J)
VENKATACHALLIAH, M.N.(CJ)

CITATION:
1994 AIR 205 1994 SCC Supl. (1) 160
JT 1993 (5) 391 1993 SCALE (3)834

ACT:

HEADNOTE:

JUDGMENT:

The Judgment of the Court was delivered by S.C. AGRAWAL, J.- These cases raise common questions involving challenge to the validity of the notification dated November 3, 1988 issued by the Government of India, whereby the earlier notification dated July 23, 1983 was amended and Item 14 of the drugs specified in the Table in the said notification was substituted so as to prohibit completely the manufacture and sale of fixed dose combination of steroids with other drugs for

internal use. The said notification has been issued in exercise of the power conferred by Section 26-A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'the Act'). In the said notification, it has been stated that the Central Government is now 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 is necessary and expedient in public interest to prohibit the manufacture and sale of the said drugs.

2. A number of manufacturers, including the appellants in Civil Appeal Nos. 2791-96 of 1992 and the petitioners in SLP (C) Nos. 9972 and 10745 of 1992 and Transferred Cases (C) Nos. 13-14 of 1992, filed writ petitions in various High Courts to challenge the validity of the said notification. One of these writ petitions (No. 364 of 1993), filed in the Madras High Court by Micro Labs (P) Ltd., was dismissed by a Division Bench of the said High Court by judgment dated June 18, 1991. SLP (C) No. 15382 of 1991 filed against the said decision was also dismissed by this Court on January 6, 19921 with the following observations:

> "The special leave petition is dismissed. The petitioner, however, will be permitted to make a fresh application for permitting manufacture and sale of drugs in question which will be considered by the Technical Board which will include one or more practising doctors specialising in treating asthma cases. The inclusion may be in the form of membership or in advisory or any other appropriate capacity."

3. Following the aforesaid decision of the Madras High Court in Micro Labs case1 a Division Bench of the High Court of Punjab and Haryana, by judgment dated June 3, 1992, dismissed a number of writ petitions wherein the validity of the notification dated November 3, 1988 had been challenged. Civil Appeals (C) Nos. 2791-96 of 1992 and SLP (C) Nos. 9972 of 1992 and 10745 of 1992 are directed against the said decision of the High Court of Punjab and Haryana. Transferred Cases (C) Nos. 13 and 14 of 1992 relate to Writ Petition No. 1701 of 1984 [Fulford India Ltd. v. Dr S.S. Gothoskar] and Writ Petition No. 1746 of 1984, [Wyeth Laboratories Ltd. v. Dr S.S. Gothoskar] which were originally filed in the Bombay High Court. The appellants in the appeals (who would be referred to as the petitioners for the sake of convenience) as well as the petitioners in special leave petitions and the transferred cases have been 1 Micro Labs (P) Ltd. v. Union of India, SLP (Civil) No. 15382 of 1991, decided on January 6, 1992 manufacturing fixed dose combinations of corticosteroids with antihistamines and corticosteroids with bronchodilators under different names. The petitioner in Writ Petition No. 364 of 1992, which has been filed under Article 32 of the Constitution, holds a licence granted by Director, Drugs Control Administration of the Government of Andhra Pradesh for the manufacture and sale of medicines and drugs. The said petitioner is not manufacturing the prohibited drugs but has submitted an application for permission to manufacture the said drugs.

4. Reference, at this stage, may be made to the relevant provisions of the Act. As stated in the preamble, the Act has been enacted to regulate the import, manufacture, distribution and sale of drugs and medicines. Section 5 of the Act provides for the constitution of the Drugs Technical Advisory Board (hereinafter referred to as 'the Board') by the Central Government to advise the Central Government and the State Governments on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it by the Act. Section 7

empowers the Central Government to constitute an advisory committee to be called as Drugs Consultative Committee (in short DCC) to advise the Central Government and the State Governments and the Board on any matter tending to secure uniformity throughout India in the administration of the Act. Section 26-A, which was introduced in the Act by Drugs Amendment Act, 1982 (Act No. 68 of 1982), provides as under:

> "26-A. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, the Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic."

5.In 1979, the DCC had set up an Experts Committee as a Sub- Committee of the DCC for screening the formulations of drugs prevalent in the Indian market from the point of view of therapeutic rationale in order to weed out irrational/harmful combination of drugs. The Sub-Committee examined a number of fixed dose combinations of drugs which did not appear to have adequate rationale or appeared to be harmful and made the following recommendation in respect of fixed dose combinations of steroids:

> "Fixed dose combinations of steroids with any other category of drugs should not be allowed as they are considered harmful for the following reasons:
>
> (a) The adrenal suppressing accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly withdrawn.
>
> (b) It is difficult to titrate the dose of a steroid when it is present in fixed dose combinations with other drugs."

6. The recommendations of the Sub-Committee were considered by the DCC in its meeting held on October 19, 1981 and in relation to steroid combinations the DCC took the following decision:

> "Fixed dose combinations of steroids for internal use should not be allowed. However, for therapeutic convenience the industry should be prevailed upon to make available preparations of steroids in lower strength e.g. Prednisolone tablet 1 mg. Fixed dose combinations of corticosteroids with other drugs are not justifiable as indiscriminate use of corticosteroids can produce serious side effects viz. fluid and electrolyte disturbances, hyperglycemia and glycosuria, increased susceptibility to infection, including tuberculosis, peptic ulcers, osteoporosis, a characteristic myopathy, Cushing's habitus, hirsutism etc. In certain clinical conditions where administration of steroid is considered necessary, the drug can be prescribed separately."

7. The recommendations of the DCC were considered by the Board at its meeting held on December 31, 1981 and the Board made the following recommendation:

> "Steroid combinations.- Fixed combinations of steroids with other drugs for internal use should not be allowed.
>
> However, the Board felt that so far as combination of steroids with other drugs for the treatment of asthma are concerned there was a need for examining the matter in further detail and getting wider medical opinion in the matter. The Board, therefore, felt that such combination may continue for the present."

8. After the incorporation of Section 26-A in the Act, notification dated July 23, 1983 was issued by the Government of India in the light of the recommendations made by the Board and the manufacture and sale of 22 drugs were prohibited under Section 26-A of the Act. Out of these 22 drugs, Items 2 to 17, including Item 14, were fixed dose combinations of certain drugs. Item 14 in the said notification was:

> "14. Fixed dose combination of Steroids for internal use except combination of Steroids with other drugs for the treatment of asthma."

9. Similar exception had been made in Item 15 relating to fixed dose combinations of chloramphenicol for fixed dose combination of chloramphenicol and streptomycin.

10.It appears that there were criticisms in various fora of the exemption granted for fixed dose combinations of steroids for treatment of asthma and medical critics opined that there is hardly a clinical situation where a fixed dose combination of corticosteroids with drugs like bronchodilators are required. Taking note of the criticism the Sub-Committee of the DCC at the meeting held on January 15, 1987 felt it necessary to review again the fixed dose combination of corticosteroids and it was decided that the manufacturers of such drugs be asked to establish published evidence of rationality for continued marketing of such combinations. It was also decided that the experts should also be requested to participate in the next meeting. At the next meeting held on June 3, 1987 the Sub-Committee was informed by the Chairman that the experts had desired that more technical data on the rationality/efficiency of the combination of drugs in the Indian context should be generated or asked for and the Sub-Committee decided that representatives of the manufacturers should be given a hearing to record their views at the next meeting and that this could be ensured by writing to pharmaceutical associations. A special meeting of experts to examine the views of the affected manufacturers who represented against withdrawal of certain formulations moving in the market was held on September 8, 1987. At the said meeting a summary of the viewpoints of the manufacturers as well as a critical review on various submissions prepared by the Director General of Health Services was placed before the experts. At the said meeting the criteria/guidelines for evaluation of each category of formulations were evolved and it was decided that the experts would evaluate the various types of formulations after going through the written submissions furnished by the affected manufacturers. The original supporting data furnished by the manufacturers was also forwarded to the experts. At the meeting of experts and the members of the Sub-Committee held on

October 16 and 17, 1987 the representations submitted by different firms against the notification on 12 categories of drugs as irrational or of doubtful efficiency were discussed by the representatives of the industry and the committee and thereafter the following recommendations were made:

> "FDC of Corticosteroids with Bronchodilators/Antihistamines for systemic use.- The Committee observed that the formulations moving in the market when administered at the recommended daily dose exceeds the safety limit of corticosteroid besides there is no rationality of FDC of corticosteroids with bronchodilators/antihistamines for the following reasons:
>
> (a)FDC of Corticosteroid with Bronchodilator.-

The recommended dose exceeds the safe limit of corticosteroid in terms of adrenal suppression. Moreover such combinations limit the scope of titration of corticosteroids which may be required in clinical situations. Such fixed dose combinations should not be allowed.

(b)FDC of Corticosteroids with antihistamines.- Antihistamine has no role in the management of bronchial asthma as histamine is released from sensitized mast cells in very high concentration near the target cells and antihistamines cannot block such effect quantitatively. Besides many more chemical mediators are released in sensitized target cells not antagonised by antihistamines.

There is a lack of published evidence to prove the higher efficacy of such combination over corticosteroid alone. Such combinations should not be allowed."

11.The Sub-Committee at its meeting held on January 15/16, 1988, noticed that the experts have opined that little will be achieved by conducting trial on these categories and have reiterated their earlier stand of recommending withdrawal of fixed dose combination of steroids with bronchodilators for systematic (sic systemic) use. The Sub-Committee has also recorded that the manufacturers of these formulations were asked through IDMA and OPPI to furnish evidence justifying their continued marketing of fixed dose combinations of corticosteroids with other drugs for internal use and the literature and any other information furnished by the manufacturers were examined by the expert groups and interested manufacturers were given an opportunity for pleading their case in person with the experts and after going through the information and literature furnished by the manufacturers and after listening to the various arguments, the experts had unanimously taken the following decision:

> "With regard to fixed dose combinations containing cortico-steroids and bronchodilators/other drugs, the experts had opined that fixed dose combinations of corticosteroids with any other drug for internal use should not be allowed because in the recommended upper dosage limit the daily dose of corticosteroids often exceeds safe pharmacological limit for adrenocortical suppression. Besides, the combinations do not permit titration of the steroid doses which is often required in practice for the administration of the minimum daily dose once a day so as to avoid adrenocortical suppression. Moreover, there is hardly any authentic reference to support that fixed

> dose combination of corticosteroids with bronchodilators or antihistamines are recommended in the treatment of asthma."

12. The Sub-Committee expressed the following view:

> "In this context, it may be pertinent to mention that the expert body and the DCC had also earlier held the same views now expressed by the expert group. As advised by the DTAB, examination of the above mentioned categories have been done and their recommendations with reasons are now placed before the DTAB for taking a final decision in the matter."

13.The matter was thereafter considered by the Board at its meeting held on April 22, 1988 and the following view was expressed:

> "The Board agreed that the fixed dose combination of chloramphenicol and streptomycin should not be allowed to be marketed.
>
> After exchange of views amongst the members it was agreed that the fixed dose combinations of corticosteroids with other drugs for use in asthma should be banned because asthma therapy is a long term therapy and corticosteroids even in low dosage when administered for longer periods are reported to cause more harm than good to the patients. The Board approved that the Entry No. 14 appearing in the notification GSR No. 578(E) dated July 23, 1983 may be suitably amended."

14.Having regard to the aforesaid recommendations of the Board, the impugned notification dated November 3, 1988 was issued whereby Item 14 contained in the earlier notification dated July 3, 1983 was substituted as under:

> "Fixed dose combination of corticosteroids with any other drug for internal use."

15.As a result of the said notification dated November 3, 1988, manufacture and sale of fixed dose combinations of corticosteroids with any other drug for internal use have been completely prohibited and the earlier exemption of such fixed dose combinations for treatment of asthma has been withdrawn.

16.In this context it may be mentioned that in Writ Petition No. 3554 of 1988 filed by M/S Roussel Pharmaceuticals pending before the Bombay High Court, the following observations were made by the High Court in an order dated February 21, 1989:

> "the Government, even at this stage, may apply its mind afresh and hear a the persons concerned on this question and then take appropriate decision."

17.In view of the said observations, the matter of prohibition of fixed dose combination of steroids with other drugs for internal use was considered afresh by a Committee of Experts. Five

manufacturers, including the two petitioners in T.C. Nos. 13 and 14 of 1992 and M/s Roussel Pharmaceuticals India Ltd. had sent their representatives to put forward their views in person, but apart from N/s Roussel Pharmaceuticals, none of the other manufacturers presented any scientific paper or any fresh evidence in support of continued marketing of fixed dose combinations of steroids for internal use. The literature which was submitted by M/s Roussel Pharmaceuticals India Ltd. had been earlier submitted by them on October 16/17, 1987. The said material and other literature on the subject was considered by the Experts Committee at the meeting held on June 6, 1989. The Experts Committee have expressed the view that the literature did not establish the rationality of administering corticosteroids with other drugs in a fixed manner for the treatment of bronchial asthma and that the published papers that were submitted by the manufacturers to justify the continued marketing of the said fixed dose combinations do not establish the necessity of using a combination of number of drugs in sub-therapeutic doses instead of using one drug in therapeutic concentration for achieving the same clinical benefit. The Experts Committee also opined that the interpretation of the results made by respective authors are not scientific. According to the Experts Committee there is no scientific evidence to show that there is a therapeutic rationality of co-administering bronchodilators, corticosteroids and sedatives in a single tablet under a fixed dose and that on the other hand there were several adverse reactions of corticosteroids when indiscriminately used. The experts have, therefore, found that there is no case for granting exemption for continued marketing of fixed dose combinations of corticosteroids with other drugs for the treatment of asthma.

18.On behalf of the petitioners, scientific data in the form of published papers in the various medical journals have been filed to show that fixed dose combination of a corticosteriod and an antihistamine is highly beneficial for the treatment of asthma. It has been submitted that the said studies reveal that the patient can obtain an equally effective treatment by consuming half the quantity of steroid and thereby the consumption of steroid is kept to the minimum possible level and further the combination has well-recognised synergistic and potentiating properties and characteristics as a result of which the treatment is far more effective for these allergic disorders than if the two drugs were taken separately. It has also been urged that as the consumption of steroid is sharply reduced, the expense involved in the treatment is also curtailed significantly. It has also been pointed out that fixed dose combinations of corticosteroids and antihistamines or bronchodilators are being marketed freely in a number of countries such as Germany, Japan, France, Switzerland, Austria etc. It has also been urged that where the patient has to take two different tablets together at the same time, it is always a serious problem to ensure that he takes both of them regularly and as required and that the problem of patient compliance is all the more acute in a country where the level of illiteracy is very high, as in India. Similarly, on behalf of the respondents, extracts from medical treatises and foreign medical journals have been filed to show that fixed dose combination of corticosteroids and antihistamines is irrational because antihistamines have no role to play in asthma management and that in respect of bronchial asthma, the standard treatment is bronchodilator and in cases of severe chronic asthma where bronchodilator alone fails to give desired result corticosteroids may be resorted to as a therapy but the dosage needs to be regulated carefully. It has been submitted that at no stage fixed dose combinations of corticosteroids with other drugs are recommended in the treatment of asthma and that such combinations were either withdrawn or never introduced for marketing in the USA, UK

etc. As regards the studies and reports that have been submitted by the petitioners, it has been pointed out that they are based on research done on animal models and no comparative study between corticosteroid alone and fixed dose combinations on human beings have been shown and further that many of the studies are not authentic publications or are obsolete. It has been submitted that no standard book or authentic medical journal speaks about fixed dose combinations of corticosteroids and other drugs in the management of asthma.

19.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 under Section 26-A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the DCC.

20.The learned counsel for the petitioners have urged that these studies and reports had been submitted on behalf of the petitioners and other manufacturers before the Sub- Committee of the DCC as well as the Experts Committee but there has been no proper consideration of the same by the experts as well as the DCC and the Board. In this context, it has been submitted that no medical expert in the field of clinical medicine in the treatment of asthma was associated in the committees and such experts alone could make a proper evaluation of the said studies. We find no substance in this contention. We have purused the minutes of the meetings of the Board, the Sub-Committee of the DCC as well as the Experts Committee. The minutes show that the material that was submitted on behalf of the manufacturers of the drugs in question was examined by the members and it is not possible to hold that there has been no proper consideration of the said material by the Experts Committee or the SubCommittee of the DCC. The complaint that experts in clinical medicine were not associated with the Committee does not appear to be justified. The minutes of the meetings of the experts to consider the views of the affected manufacturers, who represented against the proposed withdrawal of certain formulations moving in the market, which were held on September 8, 1987, October 16/17, 1987 and January 15/16, 1989 show that among the members were included Dr O.D. Gulati, Dean, CAM Medical College, Karansad and Dr J.P. Wali, Assistant Professor of Medicine, AIIMS, New Delhi. Dr M. Durairaj, Consultant, Cardiologist, Director of Cardiology, Poona Hospital and Research Centre, Pune was also member of the Sub-Committee and had attended the meeting held on January 15/16, 1988. It cannot, therefore, be said that medical experts in clinical medicine were not associated in the Experts Committee for evaluation of the material that was furnished by the manufacturers.

21.It has also been contended that in the meeting of experts held on September 8, 1987, the criteria/guidelines had been indicated for evaluation of each category of formulation and that in the said criteria/guidelines, reference is made to comparative clinical trials with the formulation. It has been urged that no such clinical trials of fixed dose combinations of corticosteroids with antihistamines or bronchodilators were conducted prior to the issuance of the impugned notification dated November 3, 1988 and in the absence of such clinical trials, the Central Government could not have been satisfied that long term use of fixed dose combinations of corticosteroids with any other drug for internal use for treatment of asthma do not have therapeutic

justification. It is no doubt true that at the meeting of experts held on September 8, 1987 certain criteria/guidelines were indicated and one of the said criteria/guidelines refers to adequate controlled comparative clinical trials with the formulation. But those criteria/guidelines were indicated in respect of 12 types of formulations which were under consideration. Combinations of corticosteroids with other drugs for systematic (sic systemic) use for the treatment of bronchial asthma was one of those formulations. With regard to fixed dose combination of chloramphenicol with streptomycin and fixed dose combination of steroids with bronchodilators for systematic use, the minutes of the meeting of the Sub- Committee held on January 15/16, 1988, record that "the experts had opined that little will be achieved by conducting clinical trials on these categories and reiterated its earlier stand of recommending withdrawal of fixed dose combination of chloramphenicol with streptomycin and fixed dose combination of steroids with bronchodilators for systematic use". This would show that the experts did not consider it necessary to conduct clinical trials in respect of fixed dose combination of steroids with bronchodilators for systematic use. The petitioners and other manufacturers, if they so desired, could have submitted fresh material based on clinical trials conducted during the period subsequent to notification dated July 23, 1983 in justification of their case before the experts. They did not, however, do so and the only produced material which was anterior to the notification dated July 23, 1983. As to whether clinical trials should have been conducted or not was primarily for the experts to decide and if the experts felt that in respect of the drugs in question such clinical trials were not necessary, it is not possible to hold that there has been no proper evaluation of the material that was submitted by the manufacturers before the Experts Committee.

22.Another contention that has been advanced on behalf of the petitioners was that under the impugned notification dated November 3, 1988, there is complete prohibition of the manufacture and sale of fixed dose combination of corticosteroids with any other drug for internal use and that such a prohibition unreasonably restricts the right of the petitioners to carry on their trade guaranteed under Article 19(1)(g) of the Constitution. The submission is that in order that the said restriction could be regarded as a reasonable restriction it was necessary for the authorities to consider whether a less drastic course could be adopted, namely, permitting manufacture and sale of such drugs with a warning about its use. Reliance, in this regard, has been placed on the observations of this Court in Mohd. Faruk v. State of Mp.2 We do not find any merit in this contention.

23.In State of Madras v. V. G. RoW3 this Court, while emphasising that "no abstract standard, or general pattern of reasonableness can be laid down as applicable in all cases" has indicated the following criteria for examining the reasonableness of the restrictions under Article 19:

> (SCR p. 607) "The nature of the right alleged to have been infringed, the underlying purpose of the restrictions imposed, the extent and urgency of the evil 2 (1969) 1 SCC 853 :(1970) 1 SCR 156 3 1952 SCR 597 : AIR 1952 SC 196: 1952 Cri LJ 966 sought to be remedied thereby, the disproportion of the imposition, the prevailing conditions at the time.....

24.In Narendra Kumar v. Union of India4 this Court has construed the term ,restriction' in Article 19 to include prohibition and has held that the reasonableness of such a restriction has to be considered "in the background of the facts and circumstances under which the order was made, taking into account the nature of the evil that was sought to be remedied by such law, the ratio of the harm caused to individual citizens by the proposed remedy, to the beneficial effect reasonably expected to result to the general public" and "whether the restraint caused by the law was more than was necessary in the interests of the general public". (SCR pp. 387-88)

25. In Mohd. Faruk v. State of Mp.2 it has been observed:

> "The Court must in considering the validity of the impugned law imposing a prohibition on the carrying on of a business or profession, attempt an evaluation of its direct and immediate impact upon the fundamental rights of the citizens affected thereby and the larger public interest sought to be ensured in the light of the object sought to be achieved, the necessity to restrict the citizen's freedom, the inherent pernicious nature of the act prohibited or its capacity or tendency to be harmful to the general public, the possibility of achieving the object by imposing a less drastic restraint, and in the absence of exceptional situations such as the prevalence of a state of emergency - national or local - or the necessity to maintain essential supplies, or the necessity to stop activities inherently dangerous, the existence of a machinery to satisfy the administrative authority that no case for imposing the restriction is made out or that a less drastic restriction may ensure the object intended to be achieved."

(SCR p. 161: SCC p. 857, para 9)

26.If the present case is considered in the light of the aforesaid tests, it cannot be said that the impugned notification prohibiting the manufacture and sale of the drug in question suffers from the vice of unreasonableness. In taking this step the Central Government appears to have moved in a cautious manner. In the earlier notification dated July 23, 1983, whereby manufacture and sale of a number of drugs, including fixed dose combinations of certain drugs was prohibited, an exception was made in respect of fixed dose combinations of corticosteroids with other drugs for the treatment of asthma. At that time also the DCC had expressed the view that fixed dose combinations of corticosteroids with other drugs were considered harmful for the reasons that (i) the adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly withdrawn; and (ii) it is difficult to titrate the dose of a steroid when it is present in fixed dose combinations with other drugs. The DCC had expressed the view that fixed dose combinations of corticosteroids with other drugs are not justifiable as indiscriminate use of corticosteroids can produce serious side effects and in certain clinical conditions where administration of steroids is considered necessary, the drug can be prescribed separately. The Board, however, felt that so far as combination of steroids with other drugs for treatment of asthma are concerned, there was need for examining the matter in further detail and getting wider opinion on the matter and therefore, the Board recommended that such combination may 4 (1960) 2 SCR 375 : AIR 1960 SC 430 continue for the present. Keeping in view the said recommendation of the

Board the Central Government excluded combination of steroids with other drugs for the treatment of asthma from the ban imposed by notification dated July 23, 1983. The matter was thereafter examined in detail by the Sub-Committee of the DCC as well as the Experts Committee in 1987-88 and the representatives of the manufacturers were given adequate opportunity of producing material in support of continued marketing of the said drugs and they were also personally heard. After taking into consideration all the relevant data that were made available, the Sub-Committee of Experts for weeding out harmful/irrational formulations expressed the same view as was held by DCC earlier and they opined that fixed dose combinations of corticosteroids with any other drug should not be allowed because in the recommended upper dosage limit the daily dose of corticosteroid often exceeds safe pharmacological limit for adrenocortical suppression and that the combinations do not permit titration of the steroid doses which is often required in practice or the administration of the minimum daily dose once a day so as to avoid adrenocortical suppression. The experts also pointed out that there is hardly any authentic reference to support that fixed dose combination of corticosteroids with bronchodilators or antihistamines are recommended in the treatment of asthma. Agreeing with the said view the Board recommended that the fixed dose combinations of corticosteroids with other drugs for use in asthma should be banned because asthma therapy is a long term therapy and corticosteroids in dosage when administered for longer periods are reported to cause more harm than good to the patients. While examining the reasonableness of the prohibition against manufacture and sale of the said drugs the harmful potentialities of the drugs have to be considered in the context of the conditions as prevalent in the country where, on account of illiteracy, people are not aware of the ill effects of the drugs available in the market and are often misled and misguided by quacks and inexperienced doctors. The less drastic course of permitting manufacture and sale of the drugs with a warning about its use, suggested by the learned counsel for the petitioner, would, in our opinion, not be adequate to protect the general public from the harmful consequences. It is, therefore, not possible to hold that the prohibition which has been imposed by the impugned notification on the manufacture and sale of the drug in question imposes an unreasonable restriction so as to be violative of the right guaranteed under Article 19(1)(g) of the Constitution.

27. The learned Additional Solicitor General has pointed out that in view of the observations made by this Court in its order dated January 6, 1992 in SLP (C) No. 1588 of 1989, the matter is being considered by the Technical Advisory Board in the light of the fresh material that has been placed before the Board. Having regard to the aforesaid observations in the order dated January 6, 1992, the petitioners as well as other manufacturers who have filed writ petitions in the High Court and whose writ petitions are pending in the High Court can also approach the Board and produce any fresh material in support of their claim for revocation of the ban on manufacture and sale of fixed dose combination of corticosteroids with any drug for internal use for treatment of asthma. The Board, while considering the matter would take into account the said material which is placed before it. The petitioners and other manufacturers desirous of availing this opportunity of reconsideration of the matter may submit the material in pursuance of this order before the Board within a period of one month.

28.It has been urged on behalf of the petitioners that on December 16, 1992, the Court had passed an interim order whereby the operation of the judgment and the order of the Punjab and Haryana

High Court dated June 3, 1992 was stayed for a period of two months and the petitioners were permitted, if they so desired, to manufacture the drug subject to the condition that the quantum of their monthly production could not exceed the monthly average of their earlier production calculated at the average of 12 months immediately preceding November 3, 1988. By order dated February 4, 1993, in the order dated December 16/17, 1992, the date November 3, 1988 was substituted by the date June 3, 1992. By order dated April 22, 1993 the period of two months was extended for a further period of four months or till the final disposal of the matter whichever was earlier. On behalf of the petitioners, it has been urged that in pursuance of the said order drugs have been manufactured by the petitioners and that the prohibition against sale should be deferred till the existing stocks are sold. Since interim directions were limited to production for a short period only on the basis of the average monthly production, there is no reason to assume that large stocks of drugs are lying with the petitioners. In the circumstances, we do not consider it appropriate to give any direction regarding permitting the petitioners to sell the existing stocks of the drugs.

29.In the result, the appeals, the special leave petitions as well as the transferred cases and writ petition are dismissed. The judgment of the High Court of Punjab and Haryana, under appeal, is affirmed subject to the direction that it would be permissible for the petitioners in these cases and other manufacturers whose writ petitions are pending in the High Courts to approach the Board and place before the Board any fresh material in support of their claim within a period of one month and any such representation as well as the material produced in support thereof shall be considered by the Board along with representation submitted in pursuance of the direction given by the Court in order dated January 6, 1992 in SLP (C) No. 15382 of 1991. This shall be ,done within three months of the filing of the representations. No order as to costs.