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Court : Mumbai

Decided On : Nov-17-1987

Reported in : AIR1988Bom134; 1988(1)BomCR134

Judge : S.M. Daud, J.

Acts : Drugs and Cosmetics Act, 1940 - Sections 5 and 26A; Constitution of India - Article 226; Drugs and Cosmetics (Amendment) Act, 1980

Appeal No. : Writ Petn. No. 836 of 1986

Appellant : Unichem Laboratories Ltd. and anr.

Respondent : Union of India (Uoi)

Advocate for Def. : S.I. Shah and;S. Sankararamakrishnan, Advs.

Advocate for Pet/Ap. : Aspi Chinoy,;F.D. Damania and;P.D. Shah, Advs.,;i/b., M.K. Ambalal and Co.

Judgement :

1. This petition under Art. 226 of the Constitution impugns the notification dated 22nd November, 1985, whereby the use of Anabolic Steroid with other drugs has been completely prohibited in purported exercise of the power conferred upon the Central Government by Section 26-A of the Drugs and Cosmetics Act, 1940 (Act No.. 23 of 1940), hereinafter referred to as 'the Drug Act'.

2. Petitioners are a pharmaceutical company engaged in the manufacture of a variety of drugs and pharmaceutical products. One of the products manufactured by them is a drug known as 'Trinergic'. The product is brought out in two forms, viz. capsules and injections. Trinergic is a combination of Anabolic Steroid known as Methandienone and Vitamins B1, B6 and B12. M/s. Ciba Geigy of Basle, Switzerland took a decision to withdraw their Anabolic Steroid, a preparation of Methandienone being marketed under the brand name 'Dianabol' from the world market. Their Indian subsidiary informed the Director General of Health Services of this decision and the reason indicated by them to the Drugs Controller was thus :

'Clinical evaluation has indicated that the balance between clinical benefit on the one hand and side-effects such as virilisation on the other, now appears to be less favourable, except possibly in osteoporosis and in the management of certain forms of anaemia. Moreover, the drug is being abused by athletes to improve their physical performance.'

On receipt of the above intimation, the Drugs Controller wrote to the Director General of Indian Council of Medical Research on May 20, 1983, to ascertain the Council's response. The matter was discussed at a meeting of experts assembled for the purpose on November 24, 1983. The meeting reached certain conclusions and the important ones which have a relevance to this petition were worded thus : --

'1. Anabolic Steroid should not be used in combination with any other class of drugs, whatsoever.

4. The package insertson Anabolic Steroids should incorporate the following :

(i) Anabolic Steroids should be administered only in the form of intermittant course, not exceeding 3 months, at a time.

(ii) If no beneficial effect is observed during this period, the drug should be discontinued.

(iii) The interval between two courses of treatment should not be less than 3 months.

(iv) There should be warning in bold letters or in a box that long term use of Anabolic Steroids can produce cancer, especially of prostate, liver and the breast.

(v) In female patients, the use of Anabolic Steroids can produce virilism which is reversible when an intermittant dosage schedule is followed; but this effect will be irreversible when prolonged treatment is given.

5. There is documentary evidence based on controlled clinical trials which has shown that the use of Anabolic Steroids in athletes does not improve the work performance of these athletes. The Group, therefore, recommended that this fact should be brought out in their product literature by the manufacturers.....

6. It should be mandatory on the part of the drug manufacturers to bring out documents such as product safeguards with respect to Anabolic Steroid compounds manufactured by them, giving information related to warning, precautions, adverse reactions and contra-indications of the product.

7. The Group was of the firm view that Anabolic Steroids should not be promoted as food substitutes under any circumstances. It is now well known that Anabolic Steroids exert their optimal effect only when adequate protein and calories intake in patient is ensured and not otherwise.

8. .....The Group was of the firm view that there was no case for banning Anabolic Steroids which constitute a useful class of drugs, provided they are used rationally and judiciously with proper precautions, asdetailed above.'

The Drugs Technical Advisory Board, functioning under Section 5 of the Drugs Act, considered the matter on 19th December, 1984 and approved the reasons which had tentatively weighed with the Government in banning the marketing of combinations of Anabolic Steroid with other drugs. Purporting to act under Section 26-A of the Drugs Act, the Central Government on 22nd November, 1985 issued the impugned notification banning the combination of Anabolic Steroid with other drugs and citing this as being necessitated because its use was (i) likely to involve

risk to human beings, and (ii) had no therapeutic justification. These two reasons rendered it necessary and expedient in the public interest to issue the ban order. The manufacturers of Trinergic, viz, the petitioners aggrieved by the ban order have come to this Court questioning the same. It is contended that there was no material in support of the decision taken by the Central Government. In so far as the Trinergic was concerned, it was a combination of Methandienone with Vitamins B1, B6 and B12. The manufacturers of this drug had been licenced by the Joint Commissioner of Food and Drugs of the Maharashtra State.

Petitioners had been selling the drug in both its forms viz. capsules and injections, since 1971. Year after year the usage of the same had been increasing. M/s. Ciba Geigy had given up the manufacture of Dianabol because the patent for the said product had expired and increasing competition from other manufacturers had made the continued manufacture of that product by them, uneconomical. In any case, what was done by M/s. Ciba Geigy could not be a precedent or a reason to explain the arbitrary decision taken by the Central Government. Here the committee of experts had been convened to discuss a ban on Anabolic Steroid. The Committee had examined the question and came to the conclusion that the Steroid was a useful product. It had recommended that the product could exert its-optimal effect only when supplemented by adequate protein and calories intake. A mix of the Steroid with Vitamins could not be said to be harmful to human life or without therapeutic justification. The petition is replete with citations from various authorities which are to the effect that Steroids with fixed dose combinations of Vitamins are not only useful, but eminently sensible in undeveloped and poverty-stricken countries, like India. Combinations of Steroid with Vitamins was permitted in several countries including advanced and developing ones. No reason had been given in support of the Committee of experts decision to prohibit the manufacture and sale of Steroid with Vitamins. The decision was void and it be struck down.

3. Respondent has filed an affidavit-in-reply through the Deputy Drugs Controller. The return refers to the decision of the Committee of experts of the Indian Council of Medical Research recommending a total ban on Anabolic Steroid in combination with other drugs. It is contended that the re was no substance in the plea of the petitioners that addition of Vitamins to the Steroid was extremely useful

or it had therapeutic justification, In fact mere combination of Vitamins to the Steroids did not contribute to the effect of Steroids, unless the patient had access to adequate quantities of proteins, carbohydrates and fat. The problem of malnutrition in India was well known and in the case of such a mal-nutritious population, addition of Vitamins to Steroids was of no assistance to the patient. In case a supplement of Vitamins was necessary to the patients who had to be given Anabolic Steroid, this could always be done by giving the Vitamins separately. Formulations containing Steroids and other drugs were being used indiscriminately and this was creating dangerous side-effects. For that purpose it was considered necessary to impose a total ban in keeping with the advice of the Board. The Government had acted in consultation with the Committee of experts and upon an approval rendered by this statutory Board. Its decision was justified under Section 26-A of the Act and was non-justiciable.

4. The short issue for determination is whether the total ban imposed on Anabolic Steroid with a combination of Vitamins B1, B6 and B12 is within the terms of Section 26-A of the Act I record a negative answer to this question and allow the petition for the reasons given below :

5. Respondent has acted on the basis of the advice tendered by the Committee of experts at its meeting held on November 24, 1983, which advice had been approved by the Board on 19th December, 1984. Section 26-A of the Act which came on the statute book by virtue of the Drugs and Cosmetics (Amendment) Act, 1980, is worded thus :--

'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, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic.'

In order to justify an action taken under this provision, the Government has to establish its satisfaction to firstly, that the use of any drug or cosmetic is likely to involve any risk to human being or animals or that the said drug does not have the therapeutic value claimed or purported to be claimed for it and, secondly, that in the public interest, it is necessary or expedient to ban or prohibit the manufacture, sale or distribution of such drug. The return tendered by the Union of India records the necessary refutations of the claims made in the petition about Trinergic being outside the pale of Section 26-A. But there is a vital difference. The petition is profusely lacked with quotations from various authorities to show that a combination of Anabolic Steroid with Vitamins is not only not harmful, but positively beneficial in various cases, including its use by suffering patients in underdeveloped countries like India. To be brief, there is a reference to the admitted position that Anabolic Steroid is a useful class of drug. The usefulness is of course conditional upon the rational use of the said Steroid. Use has to be not only rational but subject to proper precautions. Admittedly, Trinergic is not sold across the counter in India. It is available only on the production of a prescription from a Registered Medical Practitioner. The product, whether capsule or a vial of injection, is packed in cartons. On the packings the formula and inside certain precautions are set out. The accompanying literature contains the requisite warnings and indications vis-avis the drug. All the warnings that were considered necessary by the committee of experts are set out in the literature enclosed in every carton of the product. The petition contains copious citations from various authorities to show that combinations of Anabolic Steroid with Vitamins are not at all harmful. These are detailed at great length in Para 5 of the petition. The quotations are from works like Progress in Drug Research, Volume II, wherein it has been stated that such treatment is only a adjuvant form of therapy and that it must be accompanied by good quality proteins and adequate calories administration supplemented by Vitamins and Minerals, and by amelioration of the underlying disease. Next comes, a citation from the work 'Vitamins and Hormones' to be found in 'Advances in Research and Applications', Volume IV, 1946. In this work also, Vitamins of the B complex variety are said to be regarded as necessary for critical body building blocks. Para 8 of the petition gives a number of reasons why a combination of Vitamins and Anabolic Steroid is considered advantageous.

As many as nine reasons have been given and they have been summarised in the succeeding paragraph i.e. Para. 9, under five different heads, viz. :

(i) Therapeutic Synergism,

(ii) Enhanced efficiency,

(iii) Reduced side-effects,

(iv) Greater convenience for both patient and doctor,

(v) Increased compliance i.e. prevention of mistake by Medical Practitioners with inadequate knowledge of modern there peutics by preventing administration of inadequate dosage or by not providing necessary synergistic combinations.

The claim that the petitioners have put forth, is supported by certificates issued by a number of Medical Practitioners. They have given at Exh. C a list of Hospitals and Institutions which were indenting and using Trinergic for treatment of patients coming to them. These included Government, semi-Government, and public hospitals of repute. Also along with the compilation is documentation showing that Anabolic Steroid in combinations are permitted in countries like Finland, West Germany, Thailand, Indonesia and Philippines. As against this, all that the respondent has to show in support of the ban, is the action taken by Ciba Geigy. These manufacturers discontinued the manufacture of their product Dianabol. True, they gave some reasons which show that the drug was being misused. The reasons given by M/s. Ciba Geigy also purported to show that the Drug was not all that it was vaunted to be. Nonetheless, the petitioners have offered an explanation for M/s. Ciba Geigy suddenly developing qualms of conscience. They alleged that the continued manufacture of the drug had become uneconomical because the patent therefor had expired. It is quite possible that this may have been the real reason for M/s. Ciba Geigy proclaiming its desire to discontinue manufacture of a product the sale whereof had declined. But that apart, the respondent could take recourse to S. 26-A to ban a product only when the two conditions stated therein were satisfied. First, it had to be shown that Anabolic Steroid in combination with Vitamins was dangerous to human life or that it did not have the therapeutic value

claimed for the same and next, that public interest required a prohibition of its manufacture, sale or distribution. The decision reached by the Committee of experts, or the Board, does not contain the reasons in support of the conclusions reached by the said Committee or the Board. The notification issued by the Government also does no more than recite the required satisfaction. But a conclusion unsupported by reasons cannot be sustained. The return tendered by the respondent does not furnish any justification for the ban imposed by the respondent. Counsel for the respondent relies upon a Supreme Court decision in Vincent Panikurlangara v. Union of India, : [1987]2SCR468 . She contends that Section 26-A of the Act vests power in the Central Government to decide which drug should be banned and that a decision taken by the Central Government in exercise of a statutory power conferred upon it, should not be interfered with by a Court, Now it is true that the Supreme Court in the aforementioned case did caution against the intervention of Courts with decisions of authorities constituted under the Drugs Act. In fact in the decision aforementioned, it has been clearly stated that a judicial proceeding is not an appropriate medium for determination of questions that arise when the issue is whether the manufacture and sale of a drug should or should not be banned. If the Central Government had given reasons in support of ban imposed by it. I for one would not have gone further into the matter. But the position then would be that the statutory authority had discharged its task and this Court did not have the power or the expertise to examine the correctness or otherwise of the decision reached. Here, however, we have the mere ipse dixit of the Central Government which in terms rest upon the bare opinion of the Committee of experts and the Board. Therefore, such a decision cannot be sustained. Counsel for the respondent wants me to leave it to the Government to consider an application moved by the petitioners to continue the manufacture, distribution and sale of Trinergic. As late as October 13, 1987, the Central Government had turned down a similar request made by the petitioners and without giving any reason for its refusal to re-examine the matter. In any case, in the light of the material that may come before the Central Government, it can always re-examine the issue. It will not be precluded from doing so, merely because on the material before me, I will be making the rule partially absolute. This power has been recognised by the Supreme Court in the aforementioned

authority in Para 18 in the following words : --

'This being the situation, the problem has an ever-shifting base. It is commonplace that what is considered to be the best medicine today for treatment of a particular disease becomes out of date and soon goes out of the market with the discovery or invention of new drugs. Again what is considered to be incurable at any given point of time becomes subjected to treatment and cure with new finds. There is yet another situation which must be taken note of as human knowledge expands and marches ahead. With the onward march of science and complexities of the living process hither to unknown diseases are noticed. To meet new challenges, new drugs have to be found. In this field, therefore, change appears to be the rule.'

Therefore, it is not as if the Central Government's remedy to interdict the manufacture, distribution and sale of dangerous drugs is foreclosed for alt times to come. In the light of new mate rial which may be available, and, in proper exercise of the power conferred by Section 26-A of the Act, it will be at liberty to take such action as may be appropriate in the changed circumstances.

6. At the stage of admission, the learned Judge who admitted the petition had stayed the operation of the notification subject to conditions. I will make the rule absolute in terms thereof, subject to additional restriction, which I explain below :

As the position stands today, the product figuring in this petition is available on a prescription from a Registered Medical Practitioner. Such Practitioners include a large number of persons not conversant with Allopathy. This, coupled with the rumoured magic-like qualities of the product, have given rise to considerable misuse. Sportsman not limited to athletes, students preparing for tough examinations and those in search of lost vitality, are all flocking the clinics run by all manner of RMPs, who without an understanding of the drug, have been freely prescribing medicines like Trinergic. To check this misuse, it is necessary that the drug be sold upon a prescription of an RMP, subject to his having the minimum qualification of graduation in Medicine and Surgery from a recognised University. This should be made a condition for availability of the medicine from Chemists and Druggists and should be incorporated in the carton as also the in-placed literature containing the capsules or injection. Incorporation of the condition aforementioned

in the cartons and literature should come into force after 3 weeks from today. Rule in the above terms made absolute with there being no order for costs.