IN THE HIGH COURT OF JUDICATURE AT MADRAS
DATED: 26-04-2012
CORAM
THE HONOURABLE MR. JUSTICE V. RAMASUBRAMANIAN
WRIT PETITION Nos.21933 and 25442 of 2011
And M.P.Nos.1, 2 and 2 of 2011

Macleods Pharmaceuticals Limited,
Regional Office at No.44,
Perambur High Road,
Jamalia, Chennai-600 012,
Rep. by its Zonal Sales Manager
Mr.G.Elangovan .. Petitioner in WP 21933/2011

Federation of South Indian Pharmaceutical
Manufacturers Association,
Rep. by its General Secretary,
S.Lakshmi Narayanan,
Block-D1, Baid Metha Complex No.183,
Anna Salai, Saidapet,
Chennai-600 015. ... Petitioner in WP 25442/2011

Vs.

1.Union of India,
Rep.by its Secretary,
Ministry of Health and Family Welfare
FDA Bhavan, ITO Kotla Road,
New Delhi-110 002.

2.The Drug Controller General of India,
FDA Bhavan, ITO Kotla Road,
New Delhi-110 002. ... Respondents

WP 21933/2011: Writ petition filed under Article 226 of Constitution of India praying for issue of a Writ of Certiorarified Mandamus, calling for the entire records in connection with the impugned notification issued by the first respondent in GSR No.218(E) published in Gazette of India Extraordinary Part II-Section 3-Sub-section (i) dated 16.3.2011 in so far as it relates to item No.(i), i.e., Gatifloxacin formulation of systemic use in human by any route including oral and injectable and direct the respondents to review the prohibition after giving an opportunity to the petitioner.

WP 25442/2011: Writ petition filed under Article 226 of Constitution of India praying for issue of a Writ of Certiorarified Mandamus, calling for the entire records in connection with the impugned notification issued by the first respondent in GSR No.218(E) published in Gazette of India Extraordinary Part II-Section 3-Sub-section (i) No.139, dated 16.3.2011 and to quash the same in so far as it relates to item No.(i), namely 'Gatifloxacin' and direct the respondents to

review the prohibition after giving an opportunity to the petitioner.

For Petitioner in WP 21933/11 : Mr.G.Masilamani, Sr. Counsel
for M/s.King & Patridge
For Petitioner in WP 25442/11 : Mr.R.Muthukumaraswamy,
Sr. Counsel for Mr.G.Sankaran
For Respondents in both WPs : Mr.G.K.R.Pandian,
Central Government Standing
Counsel.

C O M M O N O R D E R

Both the writ petitions challenge a notification issued by the Union of India, Ministry of Health and Family Welfare, imposing a ban on the manufacture, sale and distribution of a drug by name "Gatifloxacin".

2. I have heard Mr.G.Masilamani, learned Senior Counsel as well as Mr.R.Muthukumaraswamy, learned Senior Counsel appearing for the petitioners in both the writ petitions and Mr.G.K.R.Pandian, learned Central Government Standing Counsel for the respondents.

3. The Drugs Technical Advisory Board constituted by the Central Government in terms of Section 5(1) of the Drugs and Cosmetics Act, 1940, in its 58th Meeting held on 9.11.2009, took up for consideration, under Agenda item No.8, the proposal to re-examine continued marketing of 6 drug formulations, which were reported to be prohibited or restricted in certain countries. The drug formulations taken up for review are as follows:-

1. Nimesulide (analgesic)
2. Phenylpropanolamine (PPA) (decongestant)
3. Gatifloxacin (antibiotic)
4. Tegaserod (for irritable bowel syndrome in female)
5. Deanxit (FDC of Flupenthixol and melitracen) for psychogenic depression
6. Placenta Extract

4. The Drugs Technical Advisory Board (DTAB), hereinafter referred to as the 'Board', resolved in that meeting to constitute an Expert Committee comprising of seven members, for examining the issues relating to the safety aspects of the above 6 formulations. The Board also gave liberty to the Expert Committee to co-opt experts to facilitate review of the drugs, if required.

5. It appears that in respect of 3 drugs viz., Tegaserod, Gatifloxacin and FDC of Flupenthixol, the Sub Committee convened a meeting on 27.1.2011. The Committee appears to have met thereafter on 9.2.2011 and 17.2.2011, for considering the proposal, in so far as Gatifloxacin is concerned. In the meeting held on 17.2.2011, ten persons participated. One was the Professor and Head of the Department of Pharmacology, another was a Scientist from Indian Council for Medical Research, the third was the Honorary Secretary General of the Indian Medical

Association, three were from CDSCO and four were special invitees.

6. It appears that one of the two representatives of All India Institute of Medical Sciences and the Director of Indian Veterinary Research Institute could not attend the meeting. Dr.R.R.Rai, Hony. Secretary General of the Indian Medical Association attended the meeting as representative of the said Association. One Dr.Anoop Misra of the Fortis Hospital, New Delhi, could not attend the meeting, but forwarded his recommendation on Gatifloxacin.

7. The Committee, as seen from its deliberations, took into consideration, the following facts:-

(i) that Gatifloxacin was approved by the Directorate on 3.10.2001 as a tablet and injection for the treatment of certain ailments;

(ii) that the drug is also approved as ophthalmic preparation;

(iii) that a study published in New England Journal of Medicine in March 2006 reported disturbances in blood glucose levels associated with the use of the drugs in patients of average 66 years of age;

(iv) that on 15.2.2006, M/s.Bristol Myers Squibb issued a letter to health care professionals, informing updation of warning and precautions in prescribing the drug;

(v) that the Office of the Drugs Controller General had the matter examined by the Monitoring Sub Committee of National Pharmaco-vigilance Advisory Committee (NPAC);

(vi) that the said Committee reported on 28.4.2006 that the incidence of disturbances in blood glucose levels with Gatifloxacin was very low;

(vii) that no specific reports of Dysglycemia were reported in India so far and there were no safety issues in general;

(viii) that the drug was withdrawn from the market in USA, Canada, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brazil, Mexico etc., by the originator in 2006;

(ix) that the United States Food and Drug Administration Department removed Gatifloxacin from the list of approved drugs in 2008; and

(x) that in pursuance of the recommendations of the Monitoring Sub Committee of National Pharmacovigilance Advisory Committee, the Drugs Controller General instructed all State Drug Controllers to ask the manufacturers of the drug to incorporate a "Box Warning" in the package in which the drug was sold.

8. After taking into account all the above, the Committee also appears to have perused the available published literature on the safety and efficacy of the drug and made a recommendation, in the aforesaid meeting held on 17.2.2011, for banning the drug.

9. Accepting the recommendation of the Expert Committee constituted by the DTAB, the Government of India, Ministry of Health and Family Welfare published a Notification dated 16.3.2011 in the Gazette of India, Extraordinary. The Notification reads as follows:-

"G.S.R.218(E).--Whereas the Central Government is satisfied that use of the following drugs is likely to involve certain risks to human beings and whereas safer alternatives to the said drugs are available;

and whereas the Central Government is satisfied that it is necessary and expedient to prohibit the manufacture, sale and distribution of the said drugs in public interest;

Now, therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture,

sale and distribution of the following drugs with immediate effect, namely:-

(i) Gatifloxacin formulation for systemic use in human by any route including oral and injectable; and

(ii) Tegaserod and its formulations for human use."

10. Challenging the aforesaid notification issued on 16.3.2011, in so far as the drug Gatifloxacin formulation is concerned, a Company by name Macleods Pharmaceuticals Limited, came up with the first writ petition W.P.No.21933 of 2011. It is relevant to note that though the ban order was issued on 16.3.2011, the writ petition was filed on 22.9.2011, after a gap of 6 months, drawing inspiration from a judgment delivered by this Court on 9.9.2011 in W.P.No.7458 of 2011 in respect of another drug by name Phenylpropanolamine. On 23.9.2011, W.P.No.21933 of 2011 was admitted. However, this Court ordered only notice in the petition for stay filed in M.P.No.2 of 2011.

11. While W.P.No.21933 of 2011, filed by a single manufacturer challenging the ban order on Gatifloxacin was pending, the Federation of South Indian Pharmaceutical Manufacturers Association came up with the second writ petition viz., W.P.No.25442 of 2011. The said writ petition also challenged the very same ban order dated 16.3.2011 in respect of only one drug viz., Gatifloxacin. This writ petition was filed in November 2011. On 4.11.2011, it came up for admission and the Central Government Standing Counsel took notice on behalf of the respondents. Though the writ petition was not admitted, an interim order was passed on 4.11.2011, in the second writ petition filed by the Federation of South Indian Pharmaceutical Manufacturers Association. The interim order was to the following effect:-

"Mr.Haja Mohideen Gisthi takes notice for the respondents.

There will be an interim stay in so far as sale and distribution of "Gatifloxacin" and "Tegaserod" medicines for a period of two weeks.

Post the matter on 18.11.2011."

12. Thus the interim order dated 4.11.2011 passed in W.P.No. 25442 of 2011 covered not only the drug in question viz., Gatifloxacin, but also the drug "Tegaserod", the ban of which was not under challenge. The said interim order was extended from time to time upto 22.12.2011. Thereafter it was not extended.

13. In the above circumstances, the petition for stay M.P.No.2 of 2011 in the first writ petition W.P.No.21933 of 2011 came up before me for hearing on 10.1.2012. At that time, it was brought to my notice that the judgment rendered on 9.9.2011 in W.P.No.7458 of 2011 in respect of Phenylpropanolamine had already been challenged in a writ appeal and that the writ appeal had been admitted. But no interim stay of the operation of the judgment was granted by the Division Bench, though the stay petition is pending. It was also brought to my notice that though there was no stay of the ban order in W.P.No.21933 of 2011 filed by the manufacturer, there was a stay in the second writ petition filed by the Federation of Manufacturers. Therefore, I directed the second writ petition also to be posted along with the first one, after getting appropriate orders from Hon'ble the Chief Justice. Accordingly, the second writ petition was also listed before me and the learned counsel on both sides agreed to argue the main writ petitions themselves. Therefore, the main writ petitions themselves were taken up for hearing.

14. The grounds on which the ban order is challenged, are as follows:-

(i) that the impugned order was passed under Section 26A without the advise of the DTAB;

(ii) that after constituting an Expert Committee comprising of 7 members, the tenure of Office of the DTAB itself expired and hence the issue never came up for consideration before DTAB;

(iii) that the Expert Committee constituted by DTAB comprised of 7 persons, out of whom only 2 participated in the meeting held on 17.2.2011 in which a recommendation was made for the banning of the drug;

(iv) that in the place of a nominated Expert from the Indian Medical Association, another person was allowed to participate;

(v) that the recommendation of a Doctor from Fortis Hospital appears to have been taken into account by the Expert Committee, without disclosing its contents;

(vi) that in respect of other drugs, the representatives of the pharmaceutical industry were given an opportunity of being heard by the Expert Committee, but in respect of the drug in question, none of the manufacturers was given any opportunity of presenting their Expert's view points;

(vii) that when the drug has admittedly been in the market with proper approval for 10 years, there was no urgency for the Central Government to issue the notification dated 16.3.2011, accepting the recommendation of the Expert Committee dated 17.2.2011, when DTAB was likely to be and had in fact been constituted in April 2011; and

(viii) that therefore the ban order was totally arbitrary, unjust and illegal.

15. In support of the above contentions, the learned Senior Counsel for the petitioners relied upon 4 decisions, one of the Supreme Court and one each of the Delhi, Bombay and this Court. They are:-

(i) Systopic Laboratories (Pvt.) Ltd vs. Dr.Prem Gupta {1994 Supp. (1) SCC 160}

(ii) M/s.E.Merck (India) Ltd vs. Union of India {AIR 2001 Delhi 326}

(iii) Unichem Laboratories Ltd vs. Union of India {AIR 1988 Bombay 134} and

(iv) Cipla Ltd vs. Union of india {W.P.No.7458 of 2011 dated 9.9.2011}

16. Before considering the contentions raised by the petitioners, it is necessary to have a look at the Scheme of the Act. The Act is a colonial legislation, which underwent about a dozen amendments, after independence. The object of the Act, as seen from its preamble, is to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Act is divided into 5 Chapters. While the Chapter-I is introductory and it contains the definitions of words and expressions, Chapter-II contains the provisions for the Constitution of (i) The Drugs Technical Advisory Board (ii) The Central Drugs Laboratory and (iii) The Drugs Consultative Committee. Chapter-III deals with standards of quality, misbranded drugs, adulterated drugs, spurious drugs, misbranded cosmetics, spurious cosmetics, prohibition of import of certain drugs and cosmetics, offences, confiscation and jurisdiction. Chapter-IV contains prescription regarding the manufacture, sale and distribution of drugs and cosmetics, power of the State Government to prohibit the manufacture and sale of certain drugs and cosmetics, appointment of Analysts, Inspectors etc., power of the Central Government to prohibit the manufacture, sale and distribution, penalties, cognizance of offences etc. Chapter-IV-A deals with Ayurvedic, Siddha and Unani drugs. Chapter-V contains miscellaneous provisions, including the Constitution of Special Courts, Appeals, Revisions etc.

17. Section 5(1) obliges the Central Government to constitute a Drugs Technical Advisory Board. It is seen from the language employed in Section 5(1) that the role of the Board is "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 this Act".

18. The Advisory Board is to comprise of a total of about 18 members. Sub-section (2) of Section 5 indicates the constitution of the Board as follows:-

"(i) the Director General of Health Services, ex officio, who shall be Chairman;

(ii) the Drugs Controller, India, ex officio;

(iii) the Director of the Central Drugs Laboratory, Calcutta, ex officio;

(iv) the Director of the Central Research Institute, Kasauli, ex officio;

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, ex officio;

(vi) the President of the Medical Council of India, ex officio;

(vii) the President of the Pharmacy Council of India, ex officio;

(viii) the Director of the Central Drug Research Institute, Lucknow, ex officio;

(ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government."

19. The Board once constituted will hold Office for a period of 3 years under sub-section (3) of Section 5. But a few categories of persons who are nominated or elected will hold Office so long as they hold the appointment of the other Office by virtue of which they get elected or nominated. Sub-section (4) of Section 5 enables the Board to make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it. But the bye-laws are to receive the prior approval of the Central Government.

20. Sub-section (5) of Section 5 authorises the Board to constitute Sub Committees and to appoint members of such Sub Committees. But the persons appointed to such Sub Committees should not be the members of the Board. In other words, persons who are members of the DTAB are not entitled to be members of the Sub Committees. Sub-section (6) makes it clear that the functions of the Board may be exercised notwithstanding any vacancy therein.

21. While Section 5 which deals with the constitution and role of the Drugs Technical Advisory Board is in Chapter-II, the power of the Central Government to regulate, restrict or prohibit the manufacture, sale or distribution of any drug under Section 26A is in Chapter-IV. Section 26A reads as follows:-

"26A. Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest.--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, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic.

22. A careful reading of Section 26-A shows the following:-

(i) that the power available thereunder, is to regulate, restrict or prohibit;

(ii) that such a power to regulate, restrict or prohibit, is in respect of manufacture, sale or distribution;

(iii) that the said power can be exercised in respect of any drug or cosmetic;

(iv) that to invoke such a power, the Central Government should be satisfied;

(v) that the satisfaction of the Central Government should be to the effect that the use of the drug or cosmetic is likely to involve any risk to human beings or animals and that in public interest, it is necessary to invoke the power; and

(vi) that alternatively, the satisfaction of the Central Government should be to the effect that the drug does not have therapeutic value or contains ingredients in such quantity for which there is no therapeutic justification and that in public interest, it is necessary to invoke the power.

23. Keeping in mind, the several ingredients of Section 26-A listed above, if we now have a look at the impugned notification issued by the Central Government, it is seen that the Central Government claims to have been satisfied that the use of the drug in question was likely to involve certain risks to human beings and that in view of the availability of safer alternatives, the Government thought it necessary and expedient to ban the drug in public interest. Therefore, the impugned notification, to come within the ambit of Section 26-A, should satisfy 3 requirements. They are (i) that the Central Government was satisfied; (ii) that the satisfaction was to the effect that the drug is likely to involve any risk to human beings or animals; and (iii) that the satisfaction was in public interest.

24. Before venturing to test the validity of the impugned notification on the touchstone of the parameters inbuilt in Section 26-A, it is necessary to note that Section 26-A was inserted in the Act by the Amendment Act 68 of 1982 with effect from 1.2.1983. But the original Section 26-A, as inserted by Act 68 of 1982, contained only the power to prohibit. However, by Amendment Act 26 of 2008 which came into effect from 10.8.2009, the words "regulate, restrict or prohibit" were substituted for the word "prohibit".

25. The Statement of Objects and Reasons for the Amendment Act 68 of 1982, shows that it brought forth sweeping changes in the Act, with a view to prohibit not only adulteration of drugs, but also the production of spurious and sub standard drugs, that were posing serious threat to the

health of the community. The last part of the first paragraph of the Statement of Objects and Reasons shows that the opportunity of amending the Act was availed of to incorporate certain provisions on the other aspects of effective control on the manufacture, distribution, sale of drugs and cosmetics, on the basis of experience gained in the working of the Act. Paragraph 2(3) of the Statement of Objects and Reasons, which dealt with clauses 8 and 21 of the proposed Bill, indicated that the new provision empowering the Central Government to prohibit, import or manufacture of drugs and cosmetics was in public interest.

26. As a matter of fact, the 1982 Amendment was a fall out of the report submitted by a Committee known as Hathi Committee, which comprised of about 15 members. Mr.Jaisukhlal Hathi was its Chairman and 5 members of Parliament, the Directors of Central Drugs Research Institute and National Chemical Laboratory, the Chairman of the Bureau of Industrial Costs and Prices, The Drugs Controller and the Commissioner of Food and Drug Administration of the Government of Maharashtra were its members. The Committee was constituted by the Ministry of Petroleum and Chemicals in February 1974. One of the terms of reference to Hathi Committee was "to recommend measures for effective quality control of drugs". A look at Chapter IX of the report under the caption "QUALITY CONTROL OF DRUGS" shows that even when the work of the Committee was in progress, certain unfortunate and tragic incidents connected with the quality of drugs took place in the country. This created a sense of urgency for the Committee to look into the aspect of quality control. To do so, the Committee constituted a Sub Committee. The Sub Committee's report is found in the Annexure to Chapter IX of the main report. A very important observation was recorded by the Sub Committee in para 2 of its report. The said observation may be vital for a decision in the case on hand. Therefore, it is extracted as under:-

"In the case of drugs, a little latitude shown to a manufacturer may spell all the difference between life and death."

27. Following the report of the Hathi Committee, the Central Government announced the Drug Policy in the year 1979. Thereafter, the Drug Consultative Committee set up a Sub Committee of Experts for screening the formulations of drugs prevalent in the Indian Market from the point of therapeutic rationale in order to ban harmful combinations of drugs. The Sub Committee identified at least 20 fixed dose combinations of drugs and a ban order followed. It is in this backdrop that Section 26-A was inserted in the Act by the 1982 Amendment Act.

28. Unfortunately, the vires of Section 26-A came to be challenged by vested interests in several High Courts and the power of the Central Government was crippled by interim orders passed by several Courts. In the meantime, an Advocate by name Vincent Panikurlangara, filed a public interest litigation under Article 32 of the Constitution, seeking a Mandamus to direct the Central Government to ban, in public interest, the import, manufacture, sale and distribution of drugs recommended for such banning by the Drugs Consultative Committee. While disposing of the said writ petition by a judgment rendered on 3.3.1987, reported as Vincent Panikurlangara vs. Union of India {1987 (2) SCC 165}, the Supreme Court made certain observations, which may have to be kept in mind before dealing with the contentions raised by the petitioners on the validity of the impugned ban orders. Therefore, they are briefly indicated as follows:-

(i) In paragraph 17 of the report, the Supreme Court pointed out 3 things viz., (A) that the technical aspects which arise for consideration in a matter of this type cannot be effectively handled by a Court (B) that the question of policy involved in the matter is also one for the

Union Government, keeping the best interests of the citizens in view, to decide and (C) that no final say in regard to such aspects come under the purview of the Court.

(ii) In paragraph 23 of the report, the Supreme Court reiterated "that it is not for the Court to lay down the drug policy of the Government".

29. After the 1975 report of the Hathi Committee and the Drug Policy of 1979 which led to the 1982 Amendment, the Central Government formulated two more drug policies, one in 1986 and another in 1994. Though all those policies favoured the setting up of a National Drug Authority, it did not materialise. In 1999, the National Human Rights Commission issued certain directions to the Central Government for improving the Drug Regulatory System. Following the same, a new Pharmaceutical Policy was approved in 2000. Ultimately, the Ministry of Health and Family Welfare, Government of India, constituted an Expert Committee on 27.1.2003, under the Chairmanship of Dr. R.A.Mashelkar, Director General of Council for Scientific and Industrial Research (CSIR) to undertake a comprehensive examination of Drug Regulatory Issues. One of the terms of reference to the Committee was to recommend changes required in the existing legal provisions. The report of Mashelkar Committee led to the 2008 Amendment to the Act.

30. Neither the 1982 Amendment nor the 2008 Amendment, was held unconstitutional by any Court, perhaps in view of the fact that these Amendments came as a result of the reports of Expert Committees such as Hathi Committee and Mashelkar Committee and they also came as a result of the directions issued by the Supreme Court in Vincent Panikurlangara and the directions issued by the National Human Rights Commission.

31. After the introduction of Section 26-A, the Central Government issued the first ever notification on 23.7.1983. The same was amended by another notification dated 3.11.1988. By the later notification, the Central Government banned the manufacture and sale of fixed dose combination of steroids with other drugs for internal use. The ban order came to be challenged first before a Division Bench of this Court in Micro Labs (P) Ltd vs. Union of India. The challenge was rejected by a judgment dated 18.6.1991 and the order of the Division Bench of this Court was upheld by the Supreme Court in SLP(C) No.15382 of 1991, with certain observations. Following the judgment of the Division Bench of this Court, the High Court of Punjab and Haryana dismissed several writ petitions, challenging the same notification dated 3.11.1988. The decision of the Division Bench of the High Court of Punjab and Haryana became the subject matter of a batch of civil appeals. Along with those civil appeals, the Supreme Court also took up certain writ petitions pending before the Bombay High Court and addressed various issues in its decision reported in Systopic Laboratories (Pvt.) Ltd vs. Dr.Prem Gupta {1994 Supp. (1) SCC 160}.

32. Before the Supreme Court, the manufacturers attempted to present scientific data. But in paragraph 19 of the report, the Supreme Court expressed inability to make an assessment about the relative merits of the various studies and reports placed before them. The Supreme Court pointed out in the same paragraph that "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 advise and that the Act contains provisions for obtaining such advise through the Board and DCC".

33. The argument of the manufacturers on the basis of Article 19(1)(g) of the Constitution was rejected by the Supreme Court in paragraph 22 of the report. Therefore, it is clear that any ban order imposed by the Central Government has to be tested only on the strength of the parameters laid down in Section 26-A itself and not with reference to any extraneous material, as the scope of judicial review in such matters is extremely circumscribed. Rather than throwing public interest to the winds and exposing the community at large to the risks associated with drugs that are potentially harmful, the Court could even choose to err on the wrong side.

34. With the above prelude to the scheme of the Act and the Amendments brought forth in pursuance of the reports of Expert Committees, let me now take up for consideration the grounds on which the impugned notification is challenged by the petitioners.

CONTENTION (i):

35. The first contention of the petitioners is that the impugned order was passed under Section 26-A without consulting or taking any advise from the Drugs Technical Advisory Board (DTAB) and that the requirement to act as per the advise of the DTAB is a safeguard inbuilt into Section 26-A, in order to avoid any arbitrary exercise of a sweeping power conferred upon the Central Government.

36. There is no doubt about the fact that the impugned notification was issued by the Central Government only on the advice of the Expert Committee (or Sub-Committee) constituted by the DTAB. The impugned notification was not issued on the advice of or after consultation with, the DTAB. Therefore, the question as to whether a consultation with the DTAB is mandatory or not, has to be tested with reference to the functions assigned to the DTAB under the Act and the nature of the power conferred upon the Central Government under section 26-A.

37. The functions of the DTAB are broadly indicated in Sections 5(1), 6(2), 7(1), 8(2), second proviso to Section 10, 12(1) and 33(1). They can be summarised as follows:-

(i) Under Section 5(1), the Board is constituted for the purpose of advising 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.

(ii) Under Section 6(2), the DTAB has to be consulted by the Central Government, for making rules prescribing the functions of the Central Drugs Laboratory.

(iii) But DTAB itself is obliged to receive the advise of the Drugs Consultative Committee under Section 7(1), on any matter tending to secure uniformity throughout India in the administration of the Act. Therefore, the role of the DTAB as an advisor, becomes that of an advisee under Section 7(1).

(iv) Under Section 8(2), the Central Government may amend the Second Schedule to the Act, after consultation with the Board.

(v) Under the Second Proviso to Section 10, the power of the Central Government to permit the import of any drug not being of standard quality has to be exercised after consultation with the Board.

(vi) Under Section 12(1), the rule making power of the Central Government in relation to Chapter III of the Act, has also to be exercised after consultation with or on the recommendation of the Board. But the proviso to Section 12(1) makes it clear that the Central Government can

even dispense with the requirement of consultation with DTAB, if it is of the opinion that circumstances are such that there is a necessity to make rules without consultation. However, a post-facto consultation has to be made within 6 months of making the rules.

(vii) Section 33(1) confers powers upon the Central Government to make rules for the purpose of giving effect to the provisions of Chapter-IV. It is in pari materia with Section 12(1). Therefore, the rule making power under Section 33(1) has also to be exercised by the Central Government after consultation with or on the recommendations of the DTAB. However, the consultation can be dispensed with, by virtue of the proviso to Section 33(1), subject to the condition that there is at least a post-facto consultation within 6 months of the making of the rules.

38. Thus, the Act gives in every Chapter, an indication of the functions to be exercised by the DTAB. In other words, the territory within which the DTAB is to operate and exercise its functions, is clearly demarcated in various provisions of the Act such as 5(1), 6(2), 7(1), 8(2), second proviso to Section 10, 12(1) and 33(1). But Section 26-A is completely silent about any consultation with DTAB. It is so even with Section 26-B.

39. While the advisory role of DTAB is indicated in broad and general terms in Section 5(1), it is indicated in specific terms in Sections 6(2), 7(1), 8(2), second proviso to Section 10, 12(1) and 33(1). Therefore, the absence of any reference to such requirement of consultation in Section 26-A assumes great significance. It is a well settled principle of interpretation of statutes that the Courts are not expected to supply the omission. The Parliament had consciously incorporated the expressions "after consultation with the Board" or "on the recommendation of the Board", in certain provisions of the Act such as Sections 5(1), 6(2), 7(1), 8(2), second proviso to Section 10, 12(1) and 33(1). But it has deliberately omitted to include any of those expressions while inserting Sections 26-A and 26-B. It is a case of casus omisus. Therefore, the argument that the Central Government ought to have taken the consultation of the DTAB before issuing the ban order, can hold good only if I can supply into Section 26-A, what was deliberately left out by the Parliament. This cannot be done by me and hence the first contention has to be rejected.

CONTENTION (ii)

40. The second contention is that the DTAB constituted an Expert Committee comprising of 7 members, but before the Expert Committee submitted its report, the tenure of office of the DTAB itself expired. Therefore, the DTAB never had an occasion to advise the Central Government to issue the impugned notification. But the Central Government proceeded simply on the basis of the recommendation of the Expert Committee or Sub Committee. Therefore, according to the petitioners, the impugned notification was vitiated.

41. It is seen from the pleadings that the DTAB was reconstituted by the Central Government, by a notification dated 2.2.2007, issued in pursuance of Section 5(1) and (2) of the Act. The members of the Board were to hold office for 3 years, in terms of sub-section (3) of Section 5, though they are also eligible for renomination and re-election. However, the tenure of office is not restricted, in the case of 4 categories of persons viz., (i) persons nominated from among those in-charge of Drugs Control in the States (ii) the person elected by the Executive Committee of the Pharmaceutical Council of India (iii) the person elected by the Executive Committee of the

Medical Council of India and (iv) persons holding office as Government Analysts nominated by the Central Government.

42. Therefore, the tenure of office of the members (except those covered by the proviso to sub-section (3) of Section 5) of the DTAB, expired on 1.2.2010. But even before the expiry of its tenure, the DTAB constituted an Expert Committee of 7 persons, as referred to in paras 3 and 4 of this judgment, in its 58th meeting held on 9.11.2009. Therefore, the validity of the Expert Committee, constituted by the DTAB before the expiry of its tenure, is beyond any question.

43. It is also true that the said Expert Committee made its recommendations for the ban of the drug in question, in a meeting held on 17.2.2011. It was this recommendation that was accepted by the Central Government, for issuing the impugned notification dated 16.3.2011.

44. The power of the DTAB to constitute Sub Committees and to appoint persons to Sub Committees, flows out of Section 5(5). Though Section 5(5) restricts the tenure of office of the members of the Sub Committees also to 3 years, it does not state that their tenure will be co-terminus with that of the members of the DTAB. Sub-section (5) of Section 5 reads as follows:-

"The Board may constitute Sub Committees and may appoint to such Sub Committees for such periods, not exceeding 3 years as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board."

45. The power of the DTAB under Section 5(5) comprises of two parts. The first is for the constitution of Sub Committees. The second is for the appointment of persons to such Sub Committees. The second part of the power can be exercised by the DTAB in two ways. The first is by appointing persons for a duration not exceeding 3 years. The second is by appointing persons temporarily for considering specific matters. In other words, the appointment of persons to Sub Committees, could either be tenure-specific or issue-specific. But the tenure of office of the members of the Sub Committee is not made co-terminus with the tenure of office of the DTAB itself. This is an important factor to be taken note of. Therefore, it is clear that a Sub Committee constituted under Section 5(5) will not get dissolved, automatically upon the expiry of the tenure of office of the members of the DTAB.

46. Sub-section (6) of Section 5 also makes it clear that the functions of DTAB may be exercised notwithstanding any vacancy therein. This provision assumes significance in the light of the proviso to sub-section (3) of Section 5. We have already seen that the DTAB will comprise of about 18 members, as per Section 5(2). Out of those 18 members, 8 members are ex-officio, in view of the fact that they become members by virtue of the offices that they hold either as the Director General of Health Services or as Drugs Controller of India or as Director of Central Drugs Laboratory or as Director of Central Research Institute or as Director of the Indian Veterinary Research Institute or as President of the Medical Council of India or as the President of the Pharmacy Council of India or as Director of the Central Drug Research Institute. Out of the remaining 10 members, the tenure of office of 6 persons stand protected by virtue of the proviso to sub-section (3). Those 6 persons are (i) 2 persons nominated by the Central Government from among persons in-charge of Drugs Control in the States (ii) one person elected by the Executive Committee of the Pharmacy Council of India (iii) one person elected by the Executive Committee of the Medical Council of India and (iv) 2 persons holding office as

Government Analysts nominated by the Central Government.

47. Thus out of a composition of 18 members, 8 are ex-officio and the tenure of office of 6 are protected to by the proviso to sub-section (3). In view of the fact that the members are eligible for renomination and re-election, as per Section 5(3), the tenure of office fixed by Section 5(3), is of significance only in respect of 4 out of 18 members, since 8 are ex-officio and 6 are protected by the proviso to sub-section (3).

48. The above particulars that emerge from a combined reading of sub-sections (2), (3) and (6), have to be juxtaposed with two important features of sub-section (5) viz., (i) that the appointment of members to Sub-Committees could be issue-specific or duration-specific and (ii) that the term of office of the Sub Committee is not made co-terminus with that of the DTAB.

49. Once the scheme of Section 5 in its entirety is understood properly, in the context in which the Act provides for (i) the constitution of DTAB by the Central Government and (ii) the constitution of Sub Committees by the DTAB itself, the second contention of the petitioners will easily fall to the ground.

50. The minutes of the 58th meeting of the DTAB dated 9.11.2009 show that the constitution of the expert committee under agenda No.8 was issue-specific and not duration-specific. The resolution passed by DTAB shows that the expert committee was constituted for the specific purpose of examining six drug formulations. Though seven members were nominated to the expert committee, by the resolution passed on 9.11.2009 by DTAB, the committee was also given the leverage to co-opt experts.

51. Since the expert committee constituted by DTAB was issue-specific, the submission of a report by them on 17.2.2011, after the expiry of the term of office of the DTAB, did not make the report unusable. As pointed out earlier,

(i) out of 18 members of DTAB, 8 are ex-officio and 6 have their tenure protected by the proviso to Sub-section (3) of Section 5;

(ii) the sub-committee constituted by DTAB under Section 5(5) was issue-specific and not duration-specific; and

(iii) the tenure of office of the sub-committee is not made by Section 5(5) as co-terminus with that of DTAB.

Therefore, the fact that the sub-committee submitted a report on 17.2.2011, after the expiry of the tenure of office of the members of DTAB, will not vitiate the report of the sub-committee.

52. Coupled with the fact that the functions of the DTAB are well-defined, both in general and specific terms in the Act and that Section 26A does not assign any role to the DTAB, it is crystal clear that the sub-committee's report can stand on its own. Therefore, the second contention is liable to be rejected.

CONTENTIONS (iii) and (iv)

53. The third contention of the petitioners is that the expert committee (sub-committee) constituted by DTAB comprised of seven persons out of whom, only two participated in the

meeting held on 17.2.2011 and that therefore the recommendation was by a truncated body.

54. Factually there is a small mistake in the above contention. In the meeting held on 17.2.2011, the following persons were present:-

Members :

1.Dr.Y.K.Gupta,
Prof. & Head,
Department of Pharmacology,
AIIMS, New Delhi.

2.Dr.Vijay Kumar,
Scientist-F, ICMR,
Ansari Nagar,
New Delhi-110 029.

3.Dr.D.R.Rai,
Hony. Secretary General,
Indian Medical Association (IMA),
New Delhi.

From CDSCO:

1.Dr.Surinder Singh,
Drugs Controller General (India),
CDSCO HQ. New Delhi.

2.Sh.A.K.Pradhan,
Asst. Drugs Controller (I),
CDSCO HQ. New Delhi.

3.Sh.Lalit Kishore,
Consultant,
CDSCO HQ. New Delhi.

Special Invitees:

1.Dr.M.C.Gupta,
Prof. & Head,
Department of Pharmacology,
PGIMS, Rohtak.

2.Dr.A.C.Ammini,
Prof. & Head,
Department of Endocrinology,
AIIMS, New Delhi.

3.Dr.Kartar Singh,
Prof. & Head,

Department of Gastroenterology,
PGIMER, Chandigarh.

4.Dr.R.C.Jiloha,
Prof. & Head,
Department of Psychiatry,
G.B. Pant Hospital,
New Delhi.

55. It is seen from the minutes of the meeting of the DTAB dated 9.11.2009 that the expert committee was to comprise of

1. Representative of IMA
2. Representative of ICMR
3. Professor of Medicine from a Government Institution
4. HOD of Pharmacology, AIIMS or his representatives
5. HOD of Pharmacology, NIPER, Chandigarh
6. Director, IVRI, Izzat Nager or his representative
7. DCG (I) or his representative.

56. It is interesting to note that DTAB did not name any individuals in its meeting held on 9.11.2009 as the members of the expert committee. The DTAB indicated only the broad composition of the sub-committee by referring to the institutions that may have a representation in the sub-committee. Therefore, the composition indicated by the DTAB in its meeting held on 9.11.2009 actually stood satisfied by the sub-committee which met on 17.2.2011. This can be seen from the following :

(i) the requirement to have one representative of IMA stood satisfied with the participation of Dr.D.R.Rai, Honorary Secretary General of the IMA;

(ii) the requirement to have one representative of ICMR stood satisfied with the participation of Dr.Vijay Kumar, Scientist-F, ICMR;

(iii) the requirement to have the Head of the Department of Pharmacology, AIIMS stood satisfied with the participation of Dr.Y.K. Gupta;

(iv) the requirement to have the Head of the Department of Pharmacology from NIPER, Chandigarh, stood satisfied with the participation of Dr.M.C.Gupta, who is the Professor and Head of the Department of Pharmacology in PGIMS, Rohtak;

(v) the requirement to have DCG(I) stood satisfied with the participation of Dr.Surinder Singh, Drugs Controller General (India), CDSCO, New Delhi;

(vi) the Director of the Indian Veterinary Research Institute, Izzat Nagar, though a member of the sub-committee, could not attend meeting as seen from the minutes;

(vii) though a Professor of Medicine from a Government institution was not there in the sub-committee, there were three special invitees, namely Dr.A.C.Ammini, Professor and Head of the Department of Endocrinology, AIIMS, Dr.Kartar Singh, Professor and Head of the Departmentof Gastroenterology, PGIMER, Chandigarh and Dr.R.C. Jiloha, Professor and Head of the Department of Psychiatry, G.B.Pant Hospital, New Delhi.

57. Thus, it is seen that out of seven persons nominated by the DTAB in its meeting held on 9.11.2009, five persons were there at the meeting of the sub-committee held on 17.2.2011. The sixth person namely the Director of IVRI could not be present. In so far as the seventh person namely the Professor of Medicine is concerned, there were three experts in his place, all of

whom were Professors and Heads of the Departments of Endocrinology, Gastroenterology and Psychiatry. Apart from these galaxy of experts, there were also two more persons namely the Assistant Drugs Controller (India) and a Consultant of CDSCO. Therefore, the contention that the sub-committee as constituted by the DTAB was not there at the meeting held on 17.2.2011 and that therefore its recommendations were vitiated, cannot be accepted.

58. At the cost of repetition, it should be pointed out that the DTAB did not name any individuals as members of the sub-committee. The DTAB merely indicated the institutions and the designations of persons who are to be in the sub-committee. Out of seven nominations so indicated in broad terms by the DTAB, five participated in the meeting. The absence of the other two, was more than compensated by a broad spectrum of experts numbering about five. Consequently, instead of seven members participating, ten members participated, each of whom represented different fields of expertise. Therefore, the third contention is bound to fail.

59. The fourth contention which is actually a by-product of the third contention, is that in the place of a nominated expert from the Indian Medical Association, another person was allowed to participate. But, this contention is also misconceived in view of what I have pointed out earlier namely that the DTAB did not name any individuals to the sub-committee. In the meeting held on 9.11.2009, DTAB merely indicated that a representative of IMA should be there in the sub-committee. Dr.D.R.Rai, Honorary Secretary General attended the meeting as the representative of IMA. So long as the DTAB did not name any individual, the representation of IMA by Dr.D.R.Rai cannot be questioned by the petitioners. Therefore, the fourth contention is also bound to fail.

CONTENTION (v)

60. The fifth contention is that the opinion tendered by a doctor from Fortis Hospital was taken into account by the sub-committee, but the contents of the said opinion are not reflected in the proceedings of the sub-committee.

61. A perusal of the minutes of the meeting of the sub-committee held on 17.2.2011 discloses that one Dr.Anoop Misra, Fortis Hospital could not attend the meeting, but he forwarded his recommendation on Gatifloxacin. The committee referred to his opinion only in one place, in its deliberations. But the same cannot be said to have vitiated the entire proceedings of a committee, in which at least ten experts had participated and deliberated. Moreover Dr.Anoop Misra was not a nominated member of the sub-committee. He appears to have been invited by the sub-committee. Therefore, the purpose of such invitation would stand satisfied by his providing necessary inputs rather than being physically present at the meeting. Therefore, the fifth contention also deserves to be rejected.

62. The nature of the functions performed by the sub-committee were not quasi judicial or judicial in nature. Therefore, they were not required to record every opinion tendered in black and white and deal with the same, as a court of law would do. Once the records disclose that the inputs furnished by a person who was merely an invitee, but not a member of the committee, were taken into account, that would satisfy the requirements of law, especially in the light of the nature of the functions performed by the sub-committee. Hence, the fifth contention is rejected.

CONTENTION (vi)

63. The next contention is that the representatives of the pharmaceutical industry were not given an opportunity of presenting their views before the sub-committee, in so far as this particular drug is concerned. In respect of other drugs, the representatives of the industry were given an opportunity. Therefore, the petitioners contend that the impugned proceedings are vitiated in as much as the opposite view points were not at all taken into account by the sub-committee.

64. But the above contention stems out of a misunderstanding of the scope of Section 26A. The power exercised by the Central Government under Section 26A is primarily legislative in nature and hence, the principles of natural justice have no role to play. In Drug Controller General of India Vs. W.B.Small Scale Manufacturers Association (AIR 2000 Calcutta 133), a Division Bench of the Calcutta High Court dealt with an appeal arising out of a writ petition challenging a similar ban order in respect of fixed dose combination of hydroxyquinoline group of drugs. While rejecting the contention regarding compliance with the principles of natural justice, it was held by the Division Bench as follows :

"14. Drugs and Cosmetics Act, is a complete code in itself. The said Act lays down procedures before a notification under Section 26-A of the Act can be issued. An order issued under Section 26-A of the Act by the Central Government would be in exercise of its legislative power. When such legislative power is exercised, the question of complying with the principles of natural justice would not arise. Furthermore satisfaction of the Central Government to the effect as to whether drug should be prohibited or not on the ground that the same is injurious to public health is essentially a matter dealing with a policy decision and thus, compliance of the principles of natural justice must be held to be excluded in such a situation."

65. What was laid down by the Division Bench of the Calcutta High Court, the relevant portion of which is extracted above, is a well settled proposition of law. Instead of multiplying the authorities for the said proposition, it may be useful to refer to the decision in Madras City Wine Merchants' Association and another Vs. State of Tamilnadu {1994 (5) SCC 509}. The Supreme Court pointed out in paragraph 54 of the said decision that it is a settled principle that legislative action, plenary or subordinate, is not subject to natural justice. Therefore, the fifth contention that there was violation of natural justice cannot be accepted.

66. In any case, the deliberations of the sub-committee dated 17.2.2011 disclose that opposite views were also taken into account by the committee, before arriving at its conclusion. In order to demonstrate that the sub-committee (i) took into account relevant considerations and (ii) did not take into account irrelevant considerations, it may be necessary to extract the relevant portion of the minutes of the meeting of the sub-committee, which dealt with Gatifloxacin. Therefore, it is extracted as follows :

"1. Gatifloxacin :

Committee was informed that Gatifloxacin was approved by this Directorate on 3.10.2001 as tablet (200mg/ 400mg) and injection (10mg/ml) for the treatment of acute bacterial exacerbation of chronic bronchitis/acute sinusitis/ community acquired pneumonia/uncomplicate UTI (cystitis)/ uncomplicate & urethral and cervical gonorrhoea and complicate UTI. Gatifloxacin is also approved available in the country as opthalmic preparations.

A study published in New England Journal of Medicine in March 2006 reported disturbances in blood glucose levels associated with the use of Gatifloxacin in the patients of average 66 years of age. On 15th February 2006, M/s.Bristol Myers Squibb issued letter to health care professionals informing updation of warning and precautions in the prescribing information for TEQUIN (brand name of Gatifloxacin).

The office of DCG(I) requested the monitoring sub-committee of National Pharmacovigilance Advisory Committee (NPAC) to examine the matter. The sub-committee in its meeting held on 28th April 2006 observed that the reported incidence of disturbances in blood glucose levels with Gatifloxacin is very low. Moreover, no specific reports of dysglycemia (disturbances in blood glucose levels) were reported in India so far. There is no safety issue in general. Committee gave following recommendations.

1. To incorporate warning in the label of Gatifloxacin containing products (oral and injectable) available in the country stating, 'Disturbances in blood glucose levels have been reported with use of Gatifloxacin. Elderly patients may be at particular risk for dysglycemia'.

2. To closely watch the situation before taking further action in the matter and further review the issue of ADRs associated with the Gatifloxacin in the next meeting.

3. Dr.Parthasarathi, Coordinator of Peripheral Center at JSS Medical College and Hospital, Mysore to be designated for focused ADR reporting for Gatifloxacin.

The drug was withdrawn from the market in USA, Canada, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brazil, Mexico, etc., by the originator in 2006. USFDA removed the drug from the list of approved drug products maintained by them, in 2008.

Based on the recommendations of the monitoring sub-committee of National Pharmacovigilance Advisory Committee (NPAC), office of DCG(I) on 11.8.2006 issued letters to all state drug controllers to ask all manufacturers of Gatifloxacin to incorporate the following box warning in the package insert and other promotional literature of Gatifloxacin formulations with immediate effect :

'Hypoglycaemia and hyperglycaemia may occur with the use of Gatifloxacin patients both with and without a history of diabetes. If signs and symptoms of either hypoglycaemia or hyperglycaemia occur in any patient being treated with Gatifloxacin, appropriate therapy must be initiated immediately and Gatifloxacin should be discontinued.'

The committee perused the available published literature on safety and efficacy of Gatifloxacin when administered systemically either by injectable or oral route. The committee noted that the drug had been reported to cause significant incidence of dangerous disturbance of blood glucose level particularly hypoglycaemia which may even require hospitalisation. It also noted that though the major incidence of hypoglycaemia occurred in elderly and critically ill patients, where septicaemia itself may precipitate, such incidence are much less with other available fluroquinolones and not seen with other antibiotics with a similar antimicrobial spectrum.

The committee also considered the fact that this drug has been withdrawn from most of the countries such as USA, Canada, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brazil, Mexico, etc by the innovator company. The committee also considered the opinion forwarded by Dr.Anoop Misra.

Recommendation :

The committee, therefore, is of considered opinion that the risk associated with systemic use of Gatifloxacin either by oral or injectable route over-weighs the benefit. Further, there are equally efficacious and safer antimicrobial drugs available for similar indications. Therefore,

committee recommended that systemic use of Gatifloxacin by any route including oral and injectable should be discontinued henceforth in the country.

However, committee observed that the topical use of Gatifloxacin in the form of eye ointment and eye/ear drops has not so far shown the drug to reach systemic circulation in significant concentration and cause incidence of dysglycaemia. Therefore, the committee recommended the continuation of topical use of Gatifloxacin in the form of eye ointment and eye/ear drops. However, the PMS data should be generated on at least 1000 patients within a period of one year."

67. A reading of the minutes of the sub-committee meeting extracted above shows that the sub-committee had taken into account not only relevant considerations but also both view points before they arrived at their conclusion. As a matter of fact, the sub-committee took note of -

(i) the adverse reports published in England;

(ii) the circular issued by the original manufacturer;

(iii) the recommendation made in 2006 by the National Pharmaco-vigilance Advisory Committee recording that there were no safety issues in general;

(iv) the withdrawal of the drug from the markets in USA, Canada, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brazil, Mexico, etc., by the originator himself in 2006;

(v) the removal of the drug by the United States Food and Drug Administration, from the list of approved drugs in the year 2008; and

(vi) the box warning directed to be inserted in all promotional literature of the medicine, from the year 2006.

68. Therefore, the impugned notification, issued on the basis of the recommendations of such an expert committee, cannot be found fault with on the ground that no opportunity was given to the manufacturers. The fact that the representatives of the pharmaceutical industry were given an opportunity, while dealing with other drugs such as Nimesulide, may not be a ground to make the principles of natural justice, an essential pre-requisite for the exercise of a legislative function. The note of the Drugs Controller General (India) dated 31.1.2011 is relied upon by the petitioners to show that an opportunity was given to the manufacturers of Nimesulide to make a representation, before an order was passed. But this note discloses that such an opportunity was given at the instance of the Minister to whom a representation was given by a Member of Parliament. Therefore, it is clear that the manufacturers of Nimesulide were given an opportunity, not on the basis of any statutory or other requirement, but on account of some extraneous reason, if not for extraneous considerations. Hence, the same cannot be cited as a precedent by the petitioners, to demand compliance with natural justice, in respect of a legislative power. Fortunately, despite the fact that the manufacturer of Nimesulide was granted an opportunity of hearing, that did not ultimately weigh with the Government. A ban order was imposed even in respect of that drug. Therefore, the sixth contention deserves to be dismissed.

CONTENTIONS (vii) and (viii) :

69. The petitioners contend that when the drug has admittedly been in the market with prior approval from 2001, there was no great urgency for the Government to issue the impugned notification on 16.3.2011 on the basis of the recommendation of the sub-committee dated 17.2.2011, especially when the DTAB was likely to be reconstituted within a month in April

2011. Therefore, according to the petitioners, the impugned order is arbitrary, unjust and illegal.

70. At the outset, it has to be pointed out that in matters concerning public health, the court cannot allow time to run, on the specious plea that we have already waited or suffered for ten years. If a drug is likely to be harmful or likely to involve any risk, to human beings, the withdrawal of the same from the market, should happen instantaneously, upon the acquisition of knowledge about such potentially harmful effects. It is no argument in such cases to contend that the drug has already had its harmful effect for ten years and that therefore, the redemption from the same can wait for a few months.

71. It must be remembered that under Article 47 of The Constitution, the State shall regard the improvement of public health as one of its primary duties and the State should endeavour to bring about prohibition of the consumption, of not only intoxicating drinks, but also drugs which are injurious to health. The State cannot shirk its responsibility to prohibit the manufacture and sale of drugs which are likely to involve any risk to human beings, merely on the ground that the drug is in the market for quite sometime. As pointed out by the Supreme Court in Vincent Panikurlangara, what is considered to be the best medicine today for the treatment of a particular disease, may become obsolete and go out of the market with the discovery of new generation drugs. In fact there are medicines, to which harmful bacteria develop immunity over a period of time, making the drugs lose their potency over a period of time. The withdrawal of such drugs from the market becomes a matter of imminent necessity. Recent studies show that the most famous antibiotic of the previous century namely Penicillin itself is losing its potency. The periodical development of new generation drugs by pharmaceutical companies, is not merely driven by a greed to improve their market share, but also driven by the necessity to withdraw impotent drugs and introduce highly potent drugs. Therefore, the decision to impose a ban, could not have waited for a few more months until the reconstitution of the DTAB.

72. As pointed out in para 15 above, Mr.G.Masilamani, learned Senior Counsel for the petitioner in one of the writ petitions, relied upon a few decisions. One of them is the decision of the Supreme Court in Systopic, which I have already considered in detail in an earlier paragraph. Therefore, let me now take up the other decisions for consideration.

73. In E.Merck (India) Ltd. Vs. Union of India {AIR 2001 Delhi 326}, the ban order issued under Section 26A with regard to the manufacture and sale of fixed dose combinations of vitamins B1, B6 and B12 was under challenge. While upholding the ban, a Division Bench of the Delhi High Court held in paragraph 18 that the power conferred upon the Central Government under Section 26A is neither uncontrolled nor unguided. In paragraph 19 of the said decision, the Delhi High Court made an observation that before the Government records its satisfaction under Section 26A, the opinion of the DTAB is obtained. But this observation was made by the Delhi High Court, as a passing reference, without examining the scheme of the Act with reference to various provisions that define the role of the DTAB under the Act. Therefore, this decision of the Delhi High Court cannot be taken to be laying down a law that the opinion of the DTAB is mandatory before a ban order is passed.

74. In the next decision Unichem Laboratories Ltd. Vs Union of India {AIR 1988 Bombay 134}, a ban order issued in respect of anabolic steroid was under challenge before a Single Judge

of the Bombay High Court. The ban order in question in that case had been passed on the basis of the opinion of a committee of experts and also on the basis of the withdrawal of the drug by its originator namely M/s.Ciba Geigy of Basle, Switzerland. The learned Judge of the Bombay High Court set aside the ban order on the ground that the decision reached by the committee of experts did not contain reasons in support of the conclusions and that therefore, the ban of the drug merely on the basis of the withdrawal of the drug by the originator and on the basis of the opinion of experts was not correct.

75. But with great respect, the reasonings contained in the decision of the Bombay High Court go contrary to the express provisions of the statute and the law laid down by the Apex Court. As pointed out by the Division Bench of the Calcutta High Court in Drug Controller General of India Vs W.B.Small Scale Manufacturers Association, the power exercised by the Central Government under Section 26A is legislative in nature. The same view has been expressed by the Division Bench of the Bombay High Court in paragraph 20 of its decision in E.Merck (India) Ltd, cited supra, on the basis of the decision of the Supreme Court in Cynamide India Limited (AIR 1987 SC 1802). Therefore, the reasoning given by a learned Single Judge of the Bombay High Court that such orders should be supported by reasonings, can hardly be accepted.

76. In any case, I have extracted the minutes of the meeting of the expert committee dated 17.2.2011. They do contain reasons for the conclusions reached. Exercising jurisdiction under Article 226, I am not expected to act as an appellate authority over a committee of Doctors of Super Specialities and evaluate the reasons given by them. Therefore, the decision of the Bombay High Court cannot be accepted.

77. The next decision relied upon by the learned Senior Counsel for the petitioner, is that of this Court in Cipla Ltd. Vs. Union of India. In the said decision, a learned Judge of this Court formulated five questions for consideration, in paragraph 18 of the decision. They were :

(i) Whether the prohibition is violative of Article 19(1)(g) of the Constitution of India ?

(ii) Whether the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or that any drug does not have the therapeutic value claimed or purported to have been claimed or it contains the ingredients in such quantity, for which, there is no therapeutic justification and that in the public interest, it is necessary or expedient so to do, to prohibit such drug under Section 26-A of the Act?

(iii) To arrive at such a satisfaction, whether the Central Government consulted the statutory authorities constituted under DTAB under Section 5 of the Act and have the recommendation or opinion from the expert committee constituted for the purpose of sub-section(5) of Section 5 of the Act?

(iv) Whether the opinion of the expert committee alone is enough to prohibit the drug without the recommendation of the DTAB ? and

(v) Whether this Court can exercise the power of judicial review to interfere with the order of the respondents ?

78. On the first question, the learned Judge held in paragraph 25 that there was an infringement of the fundamental right of the petitioner under Article 19(1)(g) of The Constitution, in view of the fact that the ban order was imposed only on the basis of the opinion of the expert committee constituted under Section 5(5), without there being a consultation with

the DTAB.

79. But unfortunately, the learned Judge did not take note of the role assigned to the DTAB, both in general terms and in specific terms, under Sections 5(1), 6(2), 7(1), 8(2), the second proviso to Section 10, 12(1) and 33(1). The learned Judge also did not take note of--

(i) the specific inclusion by the law makers, of the phrase "after consultation with or on the recommendations of the Board", in all these provisions of the Act, namely Sections 5(1), 6(2), 7(1), 8(2), the second proviso to Section 10, 12(1) and 33(1) and

(ii) the deliberate omission to include the said phrase in Section 26A.

Therefore, the conclusion that the learned Judge reached in paragraph 25 would be possible only if I supply the "casus omissus". But I cannot do that.

80. The doctrine of causus omissus, was expressed in a very felicitous language in CST Vs Parson Tools and Plants (1975 (4) SCC 22) as under:

'16. If the legislature willfully omits to incorporate something of an analogous law in a subsequent statute, or even if there is a causus omissus in a statute, the language of which is otherwise plain and unambiguous, the court is not competent to supply the omission by engrafting on it or introducing in it, under the guise of interpretation, by analogy or implication, something what it thinks to be a general principle of justice and equity. To do so 'would be entrenching upon the preserves of legislature' (at page 65 in Prem Nath, L.Ganesh Dass Vs. Prem Nath, L. Ram Nath (AIR 1963 Punjab 62) per Tek Chand,J.), the primary function of a court of law being jus dicere and not jus dare.'

The maxim 'judicis est jus dicere, non dare' pithily expounds the duty of the court. It is to decide what the law is and apply it; not to make it.

81. On the second question, namely whether the Central Government was satisfied in terms of Section 26A, the learned Judge recorded a finding in paragraph 31 of his judgment in favour of the petitioner. But in the discussion from paragraph 26 onwards upto paragraph 31, the learned Judge has not indicated as to how the Central Government did not reach the satisfaction as required by Section 26A. Therefore, such a finding not supported by reasons, is not binding on me.

82. The third and fourth questions taken up for consideration by the learned Judge in Cipla Ltd. were (i) as to whether consultation with DTAB was necessary and (ii) as to whether the opinion of the expert committee constituted under Section 5(5) was enough. On these questions, the learned Judge recorded a finding that consultation with DTAB was necessary and that the Government cannot proceed on the basis of the opinion of the expert committee alone.

83. But, with great respect to the learned Judge, the above findings go contrary to the scheme of the Act. I have already pointed out -

(i) that out of 18 members of the DTAB, 8 are ex-officio and 6 hold office for a term not controlled by Section 5(3), but controlled by the proviso to sub-section (3);

(ii) that the functions of the DTAB could be exercised notwithstanding any vacancy, in view of Section 5(6);

(iii) that the constitution of the sub-committee under Section 5(5) could be either issue-specific or duration-specific; and

(iv) that the term of office of the members of the sub-committee, though indicated as three

years under Section 5(5), has not been made co-terminus with that of the tenure of the members of the DTAB.

84. Therefore, there is nothing in the Act to indicate the existence of a three tier mechanism, one in the form of a sub-committee under Section 5(5), another in the form of DTAB under Section 5(1) and the third in the form of the Central Government under Section 26A, to play with the lives of the citizens of this country. When the law makers have deliberately omitted to include in Section 26A, the phrase "after consultation with or on the recommendation of the Board", despite including such a phrase in various other provisions of the Act and when the law makers have compartmentalised the constitution of the DTAB and the sub-committee under several sub-sections of Section 5, the findings recorded by the learned Judge on issue Nos.(iii) and (iv) in Cipla Ltd., appear with great respect, to be per incurium. Therefore, I am unable either to follow the same or to be compelled to refer the matter to a Division Bench.

85. On issue No.(v) relating to the scope of judicial review in such matters, the learned Judge appears to have treated the action of the Central Government under Section 26A to be an administrative action. This is clear from paragraph 75 of the decision of the learned Judge.

86. But as I have pointed out earlier, the power of the Central Government under Section 26A is legislative in nature. That it is so, has been pointed out by the Division Bench of the Delhi High Court in E.Merck (India) Ltd., on the basis of the decision of the Supreme Court in Cynamide India Ltd. The Division Bench of the Calcutta High Court has also taken the same view, in the decision in Drugs Controller General of India (cited supra).

87. As a matter of fact, judicial review is of 3 types, namely (i) judicial review of administrative action (ii) judicial review of legislative action and (iii) judicial review of judicial/quasi judicial action. The scope of every one of them is slightly different from the other. The scope of judicial review of administrative action is slightly different from the scope of judicial review of a legislative function. The Courts exercise (or expected to exercise) greater restraint with regard to the latter. Therefore, I cannot subject a ban order under Section 26A of the Act to the same tests as I would apply to an administrative action.

88. Unfortunately or fortunately, the scope of judicial review either over an administrative action or over legislative action or over quasi judicial action, is not defined in India by any statute, but is mostly judge made, based to a great extent, upon Western precedents. But in United States, there is an Act known as Administrative Procedure Act, enacted in 1946. It governs the manner in which administrative agencies of the Federal Government of the United States may propose and establish Regulations. It also provides a process for the United States Federal Courts to directly review agency decisions. As a matter of fact, this Act was enacted to regulate and standardise Federal Agency Procedures, when the Congress enacted several statutes creating new Federal Agencies as part of the "New Deal" legislative plan, designed to deliver the United States from the social and economic hardship of the Great Depression. After 60 years of its enactment, the House Judiciary Committee has undertaken a project known as "Administrative Law, Process and Procedure Project", to determine the changes that may be made to the Administrative Procedure Act. In terms of the provisions of the Act, the Reviewing Court may hold unlawful and set aside an agency action, findings and conclusion, which are

found to be -

(i) arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law;

(ii) contrary to statutory right, privilege or immunity;

(iii) in excess of statutory jurisdiction, authority, or limitations or short of statutory right;

(iv) without observance of procedure required by law;

(v) unsupported by substantial evidence in a case subject to certain provisions;

(vi) unwarranted by the facts to the extent that the facts are subject to trial de nova by the Reviewing Court.

Even the Federal Republic of Germany has an enactment known as "Administrative Procedure Act" of 1976, which applies to the administrative activities under Public Law of the official bodies. While Section 44 of the said Act lists out the circumstances under which an administrative act may become invalid, Section 45 makes it clear that an infringement of the Regulations governing procedure or form which does not render the administrative act invalid under Section 44, shall be ignored.

89. The U.S. Supreme Court has always maintained that an administrative agency's power to regulate something in public interest must always be taken to be a valid grant of authority from Congress (FDA vs. Brown and Williamson Tobacco Corp. {529 US 120 (2000)}. Consequently, Courts grant varying levels of deference to an agency's interpretation of statutes when examining questions such as whether an agency's action exceeds its congressionally delegated statutory authority.

90. In American Cynamide Co. vs. L.Richardson {456 F.2d 509}, the Commissioner of Food and Drugs required American Cynamide Company to cease the manufacture and distribution of Achrocidin compound tablets and syrup etc. The Food and Drug Administration, along with the National Academy of Science and National Research Council established panels for the purpose of reviewing the available drugs. The panel which reviewed achrocidin tablets, found them to be ineffective as a fixed combination. Therefore, FDA issued a notice of intention to ban the drug. The manufacturer claimed that the drug had widespread acceptance. But it did not submit any controlled study. Therefore, FDA did not hold any hearing. The Court refused a stay prayed for by the manufacturer, by applying the principle of deference.

91. In Weinberger vs. Hynson Westcott and Dunning Inc. {412 US 609 (1973)}, the U.S. Supreme Court showed a remarkable degree of deference to the views of the Food and Drug Administration, on the ground that the administration had the authority to determine whether a product was or was not a drug. The Court indicated that FDA should be allowed broad leeway to determine whether a drug was generally recognised as safe and effective.

92. In United States vs. Rutherford {442 US 552 (1979)}, terminally ill-patients sued FDA for access to medication not approved as yet by FDA. But the Court upheld FDA's authority to determine the effectiveness of all new drugs. The Court stated that it was reluctant to disturb a long standing administrative policy that conforms with the plain language, history and prophylactic purpose of the Act.

93. In Heckler vs. Chaney {470 US 821 (1985)}, a few prisoners convicted of capital offences and sentenced to death by lethal injection of drugs, petitioned the Food and Drug Administration,

alleging that the use of the drugs for such a purpose violated the Federal Food, Drug and Cosmetics Act. They sought a direction to the FDA to take enforcement actions to prevent those violations. The prisoners first approached the Federal District Court against the Secretary of Health and Human Services (Heckler). The District Court granted summary judgment in favour of the Secretary of Health and Human Services, holding that nothing in the Act made the decision of the FDA reviewable. The Court of Appeals reversed the decision, on the ground that FDA's refusal to take enforcement action was reviewable and that such refusal was also an abuse of discretion. But the U.S. Supreme Court reversed the said decision. While doing so, Justice Rehnquist opined as follows:-

"An agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise.

.. ..

The agency is far better equipped than the Courts to deal with the many variables involved (470 U.S. 821, 832) in the proper ordering of its priorities. Similar concerns animate the principles of administrative law that Courts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute. See Vermont Yankee Nuclear Power Corp. vs. Natural Resources Defense Council, Inc., 435 U.S. 519, 543 (1978); Train vs. Natural Resources Defense Council, Inc., 421 U.S. 60, 87 (1975)."

In his separate but concurring decision, Justice Marshall differed from the views of the other two learned Judges to some extent on the question of unreviewability of agency decisions. The note of discard was recorded by Justice Marshall in a lucid manner as follows:-

"Easy cases at times produce bad law, for in the rush to reach a clearly ordained result, Courts may offer up principles, doctrines, and statements that calmer reflection, and a fuller understanding of their implications in concrete settings, would eschew. In my view, the "presumption of unreviewability" announced today is a product of that lack of discipline that easy cases make all too easy. The majority, eager to reverse what it goes out of its way to label as an "implausible result," ante, at 827, not only does reverse, as I agree it should, but along the way creates out of whole cloth the notion that agency decisions not to take "enforcement action" are unreviewable unless Congress has rather specifically indicated otherwise. Because this "presumption of unreviewability" is fundamentally at odds with rule of law principles firmly embedded in our jurisprudence, because it seeks to truncate an emerging line of judicial authority subjecting enforcement discretion to rational and principled constraint, and because, in the end, the presumption may well be indecipherable, one can only hope that it will come to be understood as a relic of a particular factual setting in which the full implications of such a presumption were neither confronted nor understood."

However, Justice Marshall agreed with the ultimate conclusion that such agency decisions warrant deference, unless the agency had abused the discretion vested in them. He also went on to state further as follows:-

"When a statute does not mandate full enforcement, I agree with the Court that an agency is generally 'far better equipped than the Courts to deal with the many variables involved in the proper ordering of its priorities'."

The Court allowed FDA prosecutorial discretion in determining which parties it would target with enforcement actions.

94. In Young vs. Community Inst. {476 US 974 (1986)}, the Court gave deference to the FDA's decision not to promulgate a regulation that would set a safe tolerance level for a

Carcinogen found in some foods. The complexities of FDA's statutory delegation, led the Court to conclude as follows:-

"We need not find that an agency's interpretation of a statute is the only permissible construction that the agency might have adopted, but only that the agency's understanding of this very complex statute is a sufficiently rational one to preclude a Court from substituting its judgment for that of the agency."

95. Useful reference may also be made to the opinion rendered by the Fifth Chamber of the European Court of Justice in Upjohn Ltd vs. The Licensing Authority {European Court Reports 1999-I-00223}. The opinion was rendered on a reference by the Court of Appeal (England) for a preliminary ruling regarding the jurisdiction of National Courts to review the revocation of marketing authorisation of proprietary medicinal products, by competent authorities.

96. The facts in issue of the above case were as follows:-

(a) Triazolam, marketed under Upjohn's brand name Halcion, is a benzodiazepine-based prescription drug for the treatment of insomnia. Triazolam was first authorised in the United Kingdom in September 1978 for tablets in dosages of 0.25 mg and 0.125 mg.

(b) In July 1991 the Medicines Control Agency (MCA) learned from a newspaper article that a middle-aged woman had killed her mother while under the influence of Triazolam. Having sought the views of the Committee for the Safety of Medicines (CSM) which provisionally concluded that the marketing authorisations should be revoked, the MCA informed Upjohn on 2 October 1991 that the Licensing Authority had decided to suspend the marketing authorisations for that product for three months. That suspension was renewed at three-monthly intervals until 9 June 1993, the date on which the marketing authorisations were revoked.

(c) In parallel with the national procedure and in accordance with the second paragraph of Article 11 of European Union Directive 75/319, as amended, the matter was referred to the Committee for Proprietary Medicinal Products (CPMP) in October 1991 by the French Republic and the Kingdom of the Netherlands. On 11 December 1991, CPMP issued its opinion, which was against a total revocation of the marketing authorisations and requested the ad hoc rapporteurs' group appointed by the CPMP to supplement the work already done by assessing the relative risk-benefit ratios of all short-acting hypnotics, including Triazolam.

(d) However, despite that opinion, and that of the Medicines Commission recommending revocation only of the marketing authorisations relating to doses of 0.25 mg, the MCA informed Upjohn on 17 July 1992 that the Licensing Authority was proposing the definitive revocation of all marketing authorisations in respect of Triazolam. It stated that the Licensing Authority had taken into account the opinion of the CPMP of 11 December 1991.

(e) The MCA further informed Upjohn that, inasmuch as the Licensing Authority did not share the opinion of the Medicines Commission, Upjohn had the right to be heard by the 'Person Appointed' or 'Persons Appointed' by the Licensing Authority. Upjohn availed itself of that right and was heard by the Persons Appointed. Their report concluded that the benefits of Triazolam in doses of 0.25 mg and 0.125 mg outweighed the risks.

(f) On 9 June 1993 the Licensing Authority communicated to Upjohn its decision, revoking with immediate effect, all marketing authorisations relating to Triazolam. It provided a detailed statement of reasons for that decision and for its rejection of the conclusions of the Persons Appointed.

(g) On 15 September 1993, the CPMP adopted the report of the ad hoc rapporteurs' group, which concluded, in particular, that Triazolam should continue to be sold.

(h) Meanwhile, on 31 August 1993 Upjohn brought proceedings before the High Court to have the Licensing Authority's decision of 9 June 1993 quashed. It maintained in those proceedings that it was necessary, prior to any examination of the substance of the case, to request the Court of Justice to provide guidance on the way in which the National Courts should proceed in examining the case. The High Court held that there was no need to make a reference to the Court of Justice.

(i) Upjohn therefore appealed against that decision to the Court of Appeal, which decided to stay proceedings and referred the following questions to the Court of Justice for a preliminary ruling:

1. On the true construction of Council Directive 65/65/EEC as amended and in the light of Community Law generally, is it the duty of a National Court when ruling upon the compatibility with the aforesaid Community Law of a decision of a licensing authority of a Member State to revoke a license held by the manufacturer of a medicine produce to decide whether or not the said decision was the correct decision as opposed to a decision which the licensing authority could reasonably have reached on the material before it?

2. If the answer to Question 1 is that the National Court has to decide whether the decision of the competent authority was the correct decision does Community Law require it to answer that question solely on the basis of the material before the competent authority or is it obliged to look at any relevant material coming to light after the decision?

3. Was it lawful for the Licensing Authority to revoke the licence when the Committee for Proprietary Medicinal Products (CPMP) was known to the Licensing Authority to be soon to produce an opinion as to continuance of the licence?

97. While answering the first question, the European Court indicated the scope of judicial review in the following words:-

"33. As regards decisions revoking marketing authorisations taken by the competent national authorities following complex assessments in the medico-pharmacological field, it does not appear that the only appropriate means of preventing the exercise of rights conferred by Community Law from being rendered virtually impossible or excessively difficult would be a procedure for judicial review of national decisions revoking marketing authorisations, empowering the competent National Courts and Tribunals to substitute their assessment of the facts and, in particular, of the scientific evidence relied on in support of the revocation decision for the assessment made by the national authorities competent to revoke such authorisations.

34. According to the Court's case-law, where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority concerned. Thus, in such cases, the Community judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion (see, in particular, Joined Cases 56/64 and 58/64 Consten and Grundig vs. Hauptzollamt Berlin-Packhof {(1976) ECR 19}, paragraph 8, Case 9/82 hrgaard and Delvaux vs. Commission {(1983) ECR 2379}, paragraph 14, Case C-225/91 Matra vs. Commission {(1993) ECR I-3203}, paragraphs 24 and 25, and Case C-157/96 National Farmers' Union and Others {(1998) ECR I-2211, paragraph 39}."

98. Therefore, it is clear that world over, Courts have accorded deferential treatment to complex assessments made or decisions taken, by competent authorities, especially in matters concerning public health. Since public accountability of executive and legislative authorities is far greater than that of courts (at least as on date), this court is expected to avoid a path that angels fear to tread. Otherwise, courts themselves are likely to be used as a tool even by the other wings, to achieve what they wish to achieve, by arriving at right decisions through a wrong process of reasoning.

99. The case of Nimesulide presents a classic example of what I have stated in the preceding paragraph. The manufacturer of the drug Nimesulide challenged before this court, an order of the Central Government banning the drug for paediatric use. This court granted an ex parte interim stay of the ban order while admitting the writ petition. After sometime, the writ petition challenging the ban order was withdrawn. The reason given by the manufacturer was, that they came to court with the limited object of securing an interim order that would enable them to dispose of the existing stock of the drug and that they were not really aggrieved by the ban order. In other words, the drug company virtually made use of the services of this court, to dispose of the existing stock of a drug, under the pretext of challenging the ban order. I do not know how many children became victims, as there is no system of accountability. Therefore, in matters of this nature, the restraint to be exercised by courts is commensurate with the responsibility that we are burdened with.

100. As seen from the proceedings of the expert committee, a study published in New England Journal of Medicine in March 2006 reported disturbances in blood glucose levels associated with the use of the drug in patients of average 66 years of age. On 15.2.2006, M/s.Bristol Myers Squibb, the originator of the medicine issued a letter to health care professionals, informing updation of warning and precautions in prescribing the drug. The drug was withdrawn from the market in USA, Canada, Indonesia, Malaysia, Philippines, Singapore, Thailand, Brazil, Mexico etc., by the originator in 2006. The United States Food and Drug Administration Department removed Gatifloxacin from the list of approved drugs in 2008. It is on the basis of all these inputs that a committee of 10 experts in the field of medicine, recommended its ban. Therefore, the impugned ban order of the Central Government deserves deferential treatment and the challenge to the same is liable to be rejected.

101. It is well recognised that while dealing with arguments relating to improper and insufficient assessment of risk factors in cases concerning public health, the Courts are obliged to apply the "precautionary principle". In this connection, a useful reference may be made to a decision of the Court of First Instance of the European Union (III Chamber) dated 11.9.2002 in Case Nos.T-13/99 and T-70/99, brought by Pfizer Animal Health S.A. and Alpharma Inc., against the Council of the European Union. The facts leading to the said decisions are as follows:-

(i) On 23.11.1970, the European Union Council adopted Directive 70/524/EEC, laying down certain Community rules. They concerned the use of certain antibiotics both in humans and animals not only for treating bacterial infections, but also as additives in feedingstuffs as growth promoters for animals. These antibiotics are added in very low concentrations to the feedingstuffs of growing poultry, pigs and calves. The use of such antibiotics in feedingstuffs for animals is found to result in improved growth and improved weight gain, so that an animal needs

less time and less food to attain its required weight for slaughter.

(ii) But in course of time, certain bacteria in both animals and humans were found to have become resistant to certain antibiotics. This antibiotic resistance in humans became the subject matter of discussion in a Report of the European Union Conference held in Copenhagen in September 1998 under the caption "Microbial Threat".

(iii) The scientific Community acknowledged the existence of a link between the use of antibiotic as growth promoters in animals and the development of resistance to these products in humans, on the ground that the antibiotic resistance is transferable from animals to humans.

(iv) The possibility and probability of such transfer and the risk which it may entail for public health, forced the European Community and National Bodies to adopt various recommendations. These recommendations eventually led to the European Council Regulation No.2821/98 of 17.12.1998. By this Regulation, the authorisation of certain antibiotics for use as additives in feedingstuffs was withdrawn. One such antibiotic was Virginiamycin, produced by Pfizer Animal Health S.A. and another was Bacitracin Zinc, produced by Alpharma Inc.

(v) Both these companies challenged the amended Regulation of 17.12.1998. They raised four contentions in law alleging (i) breach of essential procedural requirements (ii) manifest errors of assessment (iii) infringement of fundamental principles of Community Law and (iv) breach of the obligation to state reasons.

(vi) With regard to the second plea viz., manifest errors of assessment, the contention of the companies was two fold viz., (a) that there was an error in the risk assessment; and (ii) that there was an error in the application of the precautionary principle.

102. By a decision rendered on 11.9.2002, the Court of First Instance pointed out that precautionary principle is not only one of the principles on which the Community policy on environment is based, but also that it applies to cases where Community institutions take measures to protect human health. On the contention of the companies that there was no scientific assessment of the risks, the Court elicited the following principles:-

(i) Where there is scientific uncertainty as to the existence or extent of risks to human health, Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.

(ii) Community institutions were not required, for the purpose of taking preventive action, to wait for the adverse effects of the use of the product, to materialise.

(iii) The only limiting factor on the application of the precautionary principle is that a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on a mere conjecture.

(iv) The precautionary principle can apply in situations in which there is a risk to human health, which, although it is not founded on mere hypothesis that have not been scientifically found, has not yet been fully demonstrated.

103. Therefore, the decision taken by the Sub-committee comprising of 10 experts, on the basis of the material indicated in para 100 above, is sufficient to satisfy the precautionary principle and hence the impugned order of the Central Government cannot be interfered with. Consequently, the writ petitions are liable to be dismissed. Accordingly they are dismissed as devoid of merits. No costs.

26-04-2012

Index : Yes.

Internet: Yes.
Svn/RS

To

1.The Secretary, Union of India, Ministry of Health and Family Welfare
FDA Bhavan, ITO Kotla Road, New Delhi-110 002.
2.The Drug Controller General of India, FDA Bhavan, ITO Kotla Road,
New Delhi-110 002.

V. RAMASUBRAMANIAN, J.

Svn/RS

Common Order in WP Nos.21933 and 25442 of 2011