®

IN THE HIGH COURT OF KARNATAKA AT BANGALORE

DATED THIS THE 14TH DAY OF AUGUST, 2013

BEFORE

THE HON'BLE MR. JUSTICE A S BOPANNA

W.P.No.28354/2013 (GM-RES)
c/w
W.P.Nos.32766-32768/2013 (GM-RES)

W.P.No.28354/2013

BETWEEN:

LUNDBECK INDIA PRIVATE LIMITED
A COMPANY INCORPORATED UNDER
THE PROVISIONS OF THE
COMPANIES ACT, 1956, HAVING ITS
REGISTEREED OFFICE AT
EDIFIE, 1ST FLOOR, #6, 2ND MAIN,
6TH CROSS, KODIHALLI BDA ,
HAL II STAGE, BANGALORE-08
REP. BY ITS COMPANY SECRETARY
MR. LAXMINARAYANA JOISA H **...PETITIONER**

(BY SRI SAJAN POOVAYYA, SRI HIMA LAWRENCE
& SRI VIKRAM HEGDE, ADVS.)

AND:

1. UNION OF INDIA
   REP. BY SECRETARY
   MINISTRY OF HEALTH & FAMILY
   WELFARE, NIRMAN BHAWAN
   NEW DELHI 110011

2. THE DIRECTORATE GENERAL
   OF HEALTH SERVICES
   FDA BHAVAN, ITO, KOTLA ROAD
   NEW DELHI 110 002

3. THE DRUGS CONTROLLER GENERAL INDIA
   FDA BHAVAN, ITO, KOTLA ROAD
   NEW DELHI 110 002

4. NEW DRUG ADVISORY COMMITTEE
   FDA BHAVAN, ITO, KOTLA ROAD
   NEW DELHI 110 002
   REP. BY DRUG CONTROLER &
   LICENSING AUTHORITY **... RESPONDENTS**

(BY SRI DINESH KUMAR P S, ADV. FOR R2-4)

THIS WRIT PETITION IS FILED UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA, PRAYING TO CALL FOR THE RECORDS PERTAINING TO THE DECISION OF THE CENTRAL GOVT. TO ISSUE THE NOTIFICATION DT.18.6.13, ISSUED BY THE MINISTRY OF HEALTH & FAMILY WELFARE, WHO IS R1, HEREIN VIDE ANN-AP, & ALSO RECORDS PERTAINING TO SERIAL NO.7(10) OF THE RECOMMENDATIONS OF THE NEW DRUGS ADVISORY COMMITTEE (NEUROLOGY & PSYCHIATRY) R4, HEREIN, ISSUED PURSUANT TO THE MEETING HELD ON MAY 11.2013, VIDE ANN-AN AND ETC.

W.P.Nos.32766-32768/2013

BETWEEN:

MANKIND PHARMA LIMITED
A COMPANY INCORPORATED UNDER
THE COMPANIES ACT, 1956
236, OKHLA INDUSTRIAL ESTATE
PHASE 3 NEW DELHI-110020
REP. HEREIN BY ITS
ASSISTANT GENERAL MANAGER -
LEGAL AND COMPANY SECRETARY
MR. SANJEEV KUMAR SINGH **... PETITIONER**

(BY SRI VIKRAMJIT BANARJEE, ADV. FOR
SRI H N NARENDRA DEV)

AND:

1. UNION OF INDIA
   REP. BY SECRETARY
   MINISTRY OF HEALTH AND FAMILY
   WELFARE, NIMAN BHAVAN
   NEW DELHI-110 011

2. THE DIRECTORATE GENERAL
   OF HEALTH SERVICES
   FDA BHAVAN, ITO, KOTLA ROAD
   NEW DELHI-110 002

3. THE DRUGS CONTROLLER GENERAL
   OF INDIA, FDA BHAVAN,
   ITO, KOTLA ROAD
   NEW DELHI-110 002
   REP. BY THE DRUGS
   CONTROLLER GENERAL

4. NEW DRUG ADVISORY COMMITTEE
   FDA BHAVAN, ITO, KOTLA ROAD
   NEW DELHI-110 002
   REP. BY ITS CHAIRMAN **... RESPONDENTS**

(BY SRI DINESH KUMAR, ADV.)

THESE WRIT PETITIONS ARE FILED UNDER ARTICLES 226 AND 227 OF THE CONSTITUTION OF INDIA, PRAYING TO QUASH THE NOTIFICATION DT.JUNE 18 2013 BEARING NO.292 AT PAGE 2 PASSED BY THE R-1 (ANNX-N) & DECLARE THE MINUTES OF THE MEETING DT. MAY 11 2013 OF THE NEW DRUGS ADVOSISRY COMMITTED (NEUROLOGY & PSYCHIATRY) AS NULL & VOID (ANNX-M).

THESE WRIT PETITIONS ARE HAVING BEEN RESERVED FOR ORDERS, COMING ON FOR PRONOUNCEMENT THIS DAY, THE COURT PRONOUNCED THE FOLLOWING:

O R D E R

The petitioners are before this Court assailing the notification dated 18.06.2013 bearing No.G.S.R.377(E) issued by the Ministry of Health and Family Welfare and to quash the recommendations of New Drugs Advisory Committee (Neurology & Psychiatry) ('NDAC' for short) at Sl.No.7(10) pursuant to the meeting held on 11.05.2013.

2. The petitioners are engaged in manufacturing and marketing of pharmaceutical products. Among others, they are also engaged in manufacture of 'Deanxit' which is a Fixed Dose Combination of 'Melitracen' and 'Flupenthixol'. The permission for manufacture and marketing was granted under Rule 122-B of the Drugs and Cosmetics Rules, 1945 ('1945 Rules' for short) with effect from 28.10.1998 in respect of the petitioner in W.P.No.28354/2013. The petitioners contend that the studies made on the drug has proved its safety, efficacy and benefits. It is stated to be marketed in 23 countries across the world. In India, it was introduced as a new drug by Cosme Farma Laboratories Pharmaceuticals Ltd who are the predecessors of the petitioner. The tests carried out prior to introduction of the drug is referred to in detail in the petition. The popularity of the drug as anti-depressant is also referred by indicating that for the period between June 2012 and May 2013 more than 63 lakhs prescriptions were issued.

3. The petitioner in W.P.Nos.32766-32768/2013 intended to start the Fixed Dose Combination in the year 2005. Since they were not equipped at that stage, it was manufactured by Ravenbhel Healthcare Pvt. Ltd., Jammu and Kashmir who obtained licence from the Government in the year 2005. In the year 2006-2007 Criss Pharma (India) Ltd., obtained permission from the Authorities in Uttarakhand. Subsequently the petitioners themselves are manufacturing in their unit at Himachal Pradesh from the year 2010. The petitioners herein also contend that the action taken by the respondents in issuing the impugned notification is without opportunity. Since it is the common case of both the petitioners herein except the factual variations, for all purposes, the facts relevant to the petitioners in W.P.No.28354/2013 will be noticed in the course of this order for decision making on all aspects as it is contended that they are the innovator and the result of such consideration would in any event will be relevant to both the parties since the

recommendation and notification applies to both the petitioners.

4. At an earlier point, in the year 2011 when the petitioners noticed certain news paper reports referring to the proposed ban of manufacture, supply and distribution of 'Deanxit', the petitioner in W.P.No.28354/2013 herein had approached this Court by filing a writ petition in No.7570/2011. The said writ petition was disposed of by the order dated 03.03.2011 directing the respondents to provide an opportunity of hearing to the petitioner with regard to the proposed action. Pursuant thereto, the third respondent convened the meeting of the Expert Committee along with the petitioners' representative. Since the petitioners had certain inconvenience inasmuch as the subject expert based abroad could not arrive to India on the scheduled day, the petitioners had sought for rescheduling of the meeting. Subsequently in the meeting dated 23.05.2011, the petitioner is stated to have placed sufficient material with regard to the safety

and efficacy of the drug. Despite the same, the third respondent is stated to have required the petitioners to conduct the Phase-IV clinical trial to prove the safety and efficacy profile in the 'Indian Population'. Though the petitioners were ready to undergo the same and submitted the protocol, the third respondent is stated to have changed the study protocol to the 'Special Population'. The grievance of the petitioners is that such repeated change of protocol had effected the right of the petitioners and despite the petitioner having produced sufficient material to establish the safety of the drug, the respondents without complying with the due procedure of law and contrary to the provision contained in Section 26A of the Drugs and Cosmetics Act, 1940 ('the Act' for short) has issued the impugned notification dated 18.06.2013. Since the said notification has emanated due to the recommendations of the NDAC at Subject No.7(10). The petitioners contend that the same does not reflect the fact situation and therefore is liable to be quashed.

5. The respondents through their statement of objections have sought to justify the action of the respondents. The power available to the respondents under the Act and Rules and the objective therein to regulate the import, manufacture and distribution of sale of drugs and cosmetics while preventing the spurious, adulterated and substandard drugs is referred to in detail. In that regard, the power of the Central Government under Section 26A of the Act to regulate, restrict or prohibit manufacture is also referred to. Insofar as the Fixed Dose Combination of 'Flupenthixol' with 'Melitracen', it was approved on 28.10.1998 is admitted. However, since concerns were raised in the year 2010 about the continued manufacturing and marketing before the Ministry of Health and Family Welfare as well as the Drugs Controller General (India), a sub-committee of Drugs Technical Advisory Board ('DTAB' for short) deliberated the issue on 17.02.2011 and opined that more details are to be obtained so as to arrive at their opinion. The subcommittee therefore sought for further information

and to make presentation in that regard. On 23.05.2011 the petitioners made the presentation before the committee. After deliberation, the committee decided that a well designed multi centric statistically powered Phase- IV clinical trial should be conducted to prove the safety and efficacy of the drug. The petitioner submitted the clinical trial protocol which was forwarded to the experts on 30.08.2011. On the advice of the committee, the letter dated 29.03.2012 was issued to the petitioner to modify the protocol and submit for approval. The petitioner instead of modifying the protocol, raised several issues vide their letter dated 30.03.2012.

6. The Chairman of the sub-committee forwarded his comments by letter dated 17.01.2013 about the various points arising from the protocol submitted by the petitioner is referred. Further, the doubts still not being clarified, after the presentation made on 01.03.2013 is averred and it is stated that the marketing remains questionable as 'Melitracen' is

reported as not efficacious as a single agent in depression and use of 'Flupenthixol' is associated with potentially serious neurological side effects is the contention. The protocol submitted is stated to be not proper and also the petitioners' absence in the subsequent meetings is referred. The concern expressed is that the present combination drug is not permitted in USA, UK, Denmark, Canada, Japan and Australia. Hence, it is averred that the Central Government on the recommendation made by NDAC has suspended the manufacture for sale, sale and distribution, by issue of notification dated 18.06.2013 exercising the power under Section 26A of the Act. The respondents thereby seek to justify their action.

7. Heard Sri Sajan Poovayya, Sri Vikramajit Banerjee, learned counsel for the respective petitioners and Sri P.S. Dinesh Kumar, learned counsel for the respondents who are common in both these petitions.

8. The elaborate arguments addressed by the respective learned counsel in my view would rest on two

broad issues for decision making. Firstly, as to whether the decision of the Central Government not backed by the concurrence of the DTAB is contrary to the mandate of Section 26A of the Act thereby rendering the impugned notification bad in law. Secondly, even if that is not so, whether the factual determination in the present case would justify the action taken?

9. At this stage itself, a reference to the decision of the Hon'ble Supreme Court in the case of ***Systopic Laboratories (Pvt. Ltd vs. Prem Gupta (AIR 1994 SC 205***) relied on by the learned counsel for the respondents would indicate that in the matter of the present nature where powers under Section 26A of the Act is exercised by the authorities, the right guaranteed under Article 19(1)(g) of the Constitution and the commercial interest of the manufacturers cannot be the relevant consideration. Therefore, the Court will consider only the power under the provision and the manner in which the available power has been exercised.

10. In order to appreciate the rival contentions and to determine the manner in which the power is to be exercised under Section 26A of the Act, the same is extracted herein for easy reference, which is as hereunder:

> ***"[26-A. Power of Central Government to [regulate, restrict or 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.]"*

11. The constitution and function of the DTAB on which much reliance is placed by the learned counsel for the petitioners is contained in Section 5 of the Act. The relevant portions read as hereunder:

> ***"5. The Drugs Technical Advisory Board.***- *(1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.*
>
> *(2) xxxxxxxxxxxx*
>
> *(3) xxxxxxxxxxxx*
>
> *(4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.*
>
> *(5) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.*
>
> *(6) xxxxxxxxxxxx*
>
> *(7) xxxxxxxxxxxx"*

12. Learned counsel for the petitioners, in order to contend that the exercise of power under Section 26A of the Act can only be exercised after placing the matter before the DTAB, has relied on the decision of the High Court of

Madras in the case of ***CIPLA Ltd., Represented by Depot Manager –vs- Union of India, through Secretary, Ministry of Health and Family Welfare and the Drug Controller General of India (2011(8) MLJ 281***) wherein the learned Judge while considering the validity of a notification dated 10.02.2011 issued under Section 26A of the Act prohibiting the drug "Phenylpropanolamine" vide paras 63 and 68 of the Order has held that it is mandatory on the part of the Government to take a comprehensive consultative process and advice from the DTAB.

13. Learned counsel for the respondents, on the other hand has relied on a subsequent decision of the High Court of Madras, in the case of ***Macleods Pharmaceuticals Limited and Federation of South Indian Pharmaceutical Manufacturers Association – vs- Union of India and Another (W.P.Nos.21933 and 25442 of 2011 disposed of on 26.04.2012)*** contending that 'Deanxit' was also under consideration and further on considering a similar question relating to

exercise of power under Section 26A of the Act, vis-à-vis the nature of consideration of DTAB and that too after referring to the decision in the case of '***CIPLA Ltd***.', relied on by the learned counsel for the petitioner has vide paras 79, 81 and 84 held that the recommendation of DTAB is not mandatory and has further held regarding the manner in which a matter of the present nature is to be considered.

14. Learned counsel for the petitioners, apart from seeking to distinguish the subsequent decision on facts to point out that what was considered therein was only relating to 'Gatifloxacin', and what had weighed therein was that opportunity was provided to the manufacturer therein has further relied on the decision of the Hon'ble Supreme Court in the case of ***Dr. Vijay Laxmi Sadho –vs- Jagdish (2001 (2) SCC 247)*** and a decision of a Larger Bench of this Court in the case of ***B. Haleshappa and Others –vs- State of Karnataka, by its Secretary and Commissioner, Revenue Department and Others (ILR 2002 KAR 4306)*** to

contend that it has been held in the said decisions that a Single Judge of the High Court would be bound by the earlier decision of another Single Judge of that High Court and that in case of disagreement, the matter should be referred to a Larger Bench and it is improper to characterize the earlier judgment as '*per incuriam*'. Hence, it is contended that the later decision should not be relied by this Court.

15. Though there can be no doubt whatsoever about the judicial propriety in the matter of such nature, since both the decisions, in the case of '***CIPLA Ltd.',*** *and* ***'Macleods Pharmaceutical Ltd.'***, are not by the learned Judges of the Karnataka High Court, they only have persuasive value insofar as this Court is concerned. In that view, while making an independent assessment of the legal position, it would be open for this Court to agree or not with either of the opinions and to that extent alone, the said decisions could be noticed.

16. In that backdrop, to determine the legal aspect, a perusal of Section 5(1) of the Act will indicate that the law makers have enabled the Central Government to secure advise for itself and to the State Government from the Technical Advisory Board on technical matters arising out of the administration of that Act and to carry out the other functions assigned to it by the Act. The power to be exercised by the Central Government under Section 26A is no doubt one of the functions under the Act. In that regard, a closer perusal of the provision contained in Section 26A of the Act clearly indicates that what is provided therein is the satisfaction of the Central Government. There can be no quarrel with the position that such satisfaction should be objective and based on the material available on record and cannot be fanciful and arbitrary. Thus when a notification issued thereunder becomes the subject matter of judicial review, it would be incumbent on the Central Government to rely on material to back its decision. In that circumstance, the materials being placed before the DTAB and the notification being based

on its advise would certainly make the case water tight so far as the action taken by the Central Government since the Court in such circumstance will not sit as an Appellate Authority or as super specialist when a Statutory Board constituted under the Act has also examined the matter, applied its mind and recorded its satisfaction to buttress the satisfaction of the Central Government. That by itself in my opinion cannot be the reason to come to a conclusion that for the purpose of exercise of power under Section 26A of the Act by the Central Government, it is mandatory that it has to in all circumstances be placed before the DTAB and only on its advise, the power is to be exercised. If that was the intention, the law makers would have certainly incorporated in Section 26A of the Act itself that such notification would be issued on the advise or prior consultation or approval of the DTAB. When that is not the intention, this Court cannot substitute or supply words when the plain and literal consideration of the provision conveys its intention.

17. That apart, there can be several reasons justifying the exercise of power which has to be in public interest and expedient. For instance, there could be a drug which was being manufactured and sold for a long period of time but for the reasons beyond comprehension, it may have reacted causing serious ailments or death and there could be public outcry. In such circumstance, the Central Government may have to step in immediately without loss of time and the situation may warrant exercise of power under Section 26A of the Act by regulating, restricting or prohibiting so as to contain further damage. The reasons recorded and materials available on record may satisfy the Court in the process of judicial review that there were sufficient reasons and the satisfaction of the Central Government is justified. On the other hand even in such situation, if it is expected to make it mandatory for the Central Government to follow the procedure of obtaining the experts' opinion, place it before the DTAB, wait for the eighteen members of the Board to congregate and tender its advice, it would

defeat the purpose for which such power is vested in the Central Government. In many circumstances, the fully constituted Board itself may not be available. In that direction, Section 5(1), 6(2), 7(1) and 8(2) etc., referred in the latter decision of the Madras High Court acts as an aid to construe the role of DTAB as being advisory only and would not control the power of the Central Government. The minutes of 64th meeting dated 19.07.2013 of DTAB relied on by the learned counsel for the petitioners wherein it is observed by the Board that it should be consulted in such matters before final action by the Government, cannot be treated as the mandate of law for the reasons indicated above, but it would be advisable that the Central Government to sustain their action in appropriate cases, would follow that procedure also, if it is expedient to do so.

18. Therefore, I am of the considered opinion that the prior approval of or consultation with the DTAB before exercise of power under Section 26A of the Act is not mandatory in all cases and does not make the

notification issued thereunder invalid only on that ground. However, if such consultation or advice precedes the exercise of power as being one more reason to record the satisfaction of the Central Government, that would narrow down the process of judicial review. Even if the notification is not backed by the consultation or advice of DTAB, it would still be open to the Central Government to establish before the Court that the satisfaction recorded is sufficient in the facts and circumstances arising in a particular case.

19. In the light of the above conclusion on the first aspect, the issue for consideration is, whether on the facts emerging herein the action is justified. As such, it is necessary to advert to the fact situation. The undisputed fact is that 'Deanxit' which is a Fixed Dose Combination' of 'Flupenthixol' and 'Melitracen' was permitted to be manufactured in India with effect from 28-10-1998. According to the petitioners, it became an extremely efficacious anti depressant drug with an average annual prescription of 63 lakhs. The

respondents however contend that certain concerns were raised in the years 2010 about the continued manufacturing and marketing before the Ministry of Health and Family Welfare as well as the Drugs Controller General (India). In that regard, the Sub-Committee of DTAB deliberated on 17.02.2011 the issue of continued marketing and opined that more data should be acquired on the rationality of the combination; the reason for the combination not being available in other developed countries; the safety and efficacy of the combination. Therefore, details were sought from the companies engaged in manufacturing the drug. It is from this stage the dispute has started between the parties with regard to the procedure followed and the extent of opportunity granted. On this aspect, though the learned counsel for the respondents has referred to the decision of the High Court of Madras in the case of ***Macleods Pharmaceuticals Limited*** to state that 'Deanxit' was the subject matter therein, the said reference is only with reference to the matters considered by the DTAB in its meeting held on

09.11.2009 wherein it was taken up for consideration to propose that it has to be re-examined but what arose for consideration by the Madras High Court in the case was only 'Gatifloxacin'. But in the instant case, the question is as to whether the Expert Committee has rendered any finding about the safety and efficacy of the use of the drug so as to suspend manufacture and in that regard the satisfaction arrived at by the Central Government needs to be examined.

20. To consider this aspect of the matter, apart from noticing the contentions in the objection statement I have also referred to the observations and recording in the copy of the note sheet of the file made available by the learned counsel for the respondents. On 17.02.2011, the sub-committee of the DTAB consisting of experts viz.,

1. Dr. R. C. Jilowa, Prof. & Head, Department of Psychiatry, G.B. Part Hospital, New Delhi.
2. Dr. Y.K. Gupta, Prof. & Head, Department Pharmacology, AIIMS, New Delhi.

3. Dr. M.C. Gupta, Prof. & Head Department Pharmacology, PGIMS, Rohtak.
4. Dr. A.C. Ammini, Prof. & Head, Department of Endocrinology, AIIMS, New Delhi.
5. Dr. Kartar Singh, Prof. & Head, Department of Gasteronerology, PGIEMR, Chandigarh.
6. Dr. D.R. Rai, Hon. Secretary General, IMA, New Delhi. Dr. Vijayakumar, Scientist–F, ICMR, Ansari Nagar, New Delhi, had met and deliberated.

21. The deliberation resulted in opining to seek more data on the rationality of the combination; the reason for not being available in other developed countries and the safety and efficacy so as to arrive at an opinion. Hence presentation was sought before the Expert Committee. What is significant according to my observation is that except for raising a doubt and seeking clarification, there is no reference or material relied upon the definite feed back about the ill-effects despite the combination being in the field for more than

12 years. Though hearing dates had been fixed and rescheduled at the instance of the petitioners, the fact that the petitioners through their subject expert participated in the meeting held on 23.05.2011 is evident. The petitioner is stated to have submitted the published articles, Global Clinical studies and period safety update report. The file noting of the respondents also refers to the fact that a detailed presentation was made and after deliberation the committee decided that " A well- designed multicentric statically powered Phase-IV Clinical trial should be conducted after taking due approval from DCG (I) office to prove safety and efficacy profile in Indian Population within a period of one year before it is considered further". Even at this stage, it is seen that nothing adverse is recorded but what was required was Clinical trial in population, which would mean that manufacture and sale was to continue and Clinical trial was to be conducted. Though protocol was submitted by the petitioner on 30.08.2011, the respondents by their letter dated 29.03.2012 advised to modify the protocol, which was also submitted and

forwarded to the Chairman of the committee on 06.11.2012, who by his letter dated 17.01.2013 forwarded his comments on the Clinical trial protocol and raised points, but before any further action is taken, based on the report submitted by Ministry, DCG (I) has addressed letter dated 10.01.2013 in the meanwhile.

22. Thus when the Clinical trial protocol was still being worked out, the sudden concern raised by the Department related Parliament Standing Committee on Health and Family Welfare had intervened in the process of following the due procedure and it merely referred to the position in other developed countries. Further after the presentation before the NDAC on 01.03.2013 and after deliberation, it was of the view that rationality and essentiality of continued marketing is questionable as 'Melitracen' is reported to be not efficacious as a single agent in depression and the use of 'Flupenthixol' is associated with potentially serious neurological side effects. The reason and basis for such

conclusion is not supported by the source of such impression or materials but the only reason indicated is that various other more efficacious, safe and relatively inexpensive alternate anti-depressants and anti-anxiety drugs are already available. Even that conclusion is not supported by material particulars. Yet, what cannot be ignored is that at that stage also, the Phase-IV protocol was being re-worked. The reason indicated thereafter is that the petitioner did not participate in the meeting held on 11.05.2013 and as such suspension is recommended. But it was advised that the firm may generate data on safety, tolerability and efficacy of the drug for further consideration in the matter. At the same time, the Department related Parliament Standing Committee in its 66th report sought immediate action on the ground that people of India should not consume a questionable drug approved in a questionable manner when innovator country Denmark is not allowing its use. Again at this point also, there is no indication about the reason for arriving at the conclusion that the

efficacy and safety is questionable despite the drug being available for a long time.

23. In order to contend that the drug has not been prohibited in Denmark but was not registered in the circumstance that it was not sought for, reliance is placed on Annexure-K. Though that may not be the issue, even from the recommendation of the NDAC as noticed from the file notings or the extract as found in Annexure-AN at item 7(10), it does not indicate satisfaction of the committee based on any adverse materials or studies but attributes it to the default of the petitioner in not making the presentation on 11.05.2013. But, on the other hand, there is no reference to the detailed presentation which admittedly had been done on 23.05.2011 and a Phase-IV Clinical trial, that was desired at that stage. No doubt, by the impugned notification the manufacture for sale and distribution has only been suspended. The procedure followed however does not indicate that there has been an objective assessment and satisfaction recorded in

that regard as to why such apprehension regarding efficacy and safety has arisen in respect of an existing drug and the basis to conclude that it involves risk to human beings or that it does not have the therapeutic value. Neither has the dissatisfaction relating to the presentation is recorded.

24. In that background, reference to the decision in the case of ***Unichem Laboratories Ltd., Bombay & another –vs- Union of India (AIR 1988 Bombay 134)*** relied on by the learned counsel for the petitioner would indicate that the Court in that case also after arriving at the conclusion that the action is not supported by reasons to record the satisfaction of the Central Government had held it as unsustainable, thereafter leaving it open for re-examination. In the meanwhile, the sale was permitted subject to restrictions. Further, in the case of ***Roussel Pharmaceuticals (India) Ltd. –vs- Union of India (1989 (42) ELT 374 (Bom)),*** the High Court of Bombay while considering the case at the stage of interim order

was of the view that the Government has not demonstrated at that stage that ban is based upon the relevant material. Hence, while granting interim relief and issuing Rule, had permitted the Government to apply its mind afresh at that stage.

25. In the instant case also, on referring to the fact situation, I have arrived at the conclusion that the procedure followed does not indicate the consideration of definite materials to record the satisfaction of the Central Government. Hence, certainly in the instant case also, the matter would require reconsideration before a final decision is taken by the Central Government as it is for the experts to take the final decision, but after following the due procedure since in any event neither this Court has the wherewithal nor the expertise to decide whether the drug is safe and efficacious while referring to it in the process of judicial review. In the instant case, the impugned notification has only suspended the manufacture and sale and the Expert Committee while recommending the suspension

has also indicated that an opportunity be granted to the petitioners to generate data on safety, tolerability and efficacy of the drug for further consideration and that has been reiterated before this Court also by the learned counsel for the respondents.

26. The question which therefore arises for further consideration is as to whether the impugned notification is to be quashed at this stage or should this Court allow the respondents to complete the reconsideration and take a decision as to whether it should be revoked or to proceed further in the matter. In a matter relating to public health when there is a regulatory mechanism and even if the process followed is not appropriate, but if the ultimate decision points to circumstance of there being dangerous consequence if the drug is allowed to be marketed, the Courts should be slow to pass such orders in cases where if such sale is permitted, it may be detrimental to public health.

27. However, in the instant petitions, apart from the procedure not being followed, I have already noticed

that except for requiring the petitioners to establish the efficacy and safety of an existing drug and the Expert Committee broadly observing that 'Melitracen' is reported to be not efficacious as single agent in depression and 'Flupenthixol' is associated with 'potential' serious neurological side effects and that other inexpensive alternate antidepressants are available, there is no indication of dire consequences of an emergent nature. Further, the notification appears to be a result of the knee-jerk reaction of the Department related Parliament Standing Committee on Health and Family Welfare, though the Expert Committee was still at the stage of requiring Phase-IV Clinical trial. Whether such Phase-IV Clinical Trial is to be conducted on 'Indian Population' or 'Special Population,' the same can be done only if the drug is available and prescribed. Further the drug would be available only on the prescription of a Medical Practitioner. That apart the Expert Committee itself has required the firm to generate data on safety, tolerability and efficacy. All the above would not be possible, if the

suspension is continued. At the same time, since I have opined that this Court has not upheld the efficacy and safety but would require reconsideration, until the said process is completed, it would still be open for the Central Government to regulate the manufacture and sale of the drug by imposing such conditions, requirement and compliances as the same is also permissible under Section 26A of the Act. Hence, the impugned recommendation and the notification are liable to be quashed with the liberty to the Central Government.

28. In the result, the following:

ORDER

i) The Writ Petition No.28354/2013 and W.P.Nos.32766-768/2013 are allowed in part.

ii) The recommendation dated 11.05.2013 of the NDAC at Sl.No.7(10) and the notification dated 18.06.2013 in No.G.S.R.377(E) issued by the Ministry of Health and Family Welfare

stand quashed subject to the observations and liberty granted to the respondents in the body of the order.

iii) The matter stands remanded to the respondents No.2 and 3 to reconsider afresh and take a decision one way or the other in accordance with law.

iv) Pending reconsideration, the respondents shall have the liberty to regulate the manufacture and sale in the manner as observed supra by imposing such conditions if need be.

v) IA No.2/2013 filed in W.P.No.28354/2013 stands disposed of as unnecessary since the applicants therein are the petitioners in W.P.Nos.32766-32768/2013.

vi) Parties to bear their own costs.

Sd/-
JUDGE

Akc/bms