REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 22972 OF 2017
(ARISING OUT OF SLP (C) NO.7061 OF 2017

UNION OF INDIA AND ANR. …APPELLANTS

VERSUS

PFIZER LIMITED AND ORS. ...RESPONDENTS

WITH

CIVIL APPEAL NOS. 22973-22981 OF 2017
(ARISING OUT OF SLP (C) NO.10170-10178 OF 2017)

CIVIL APPEAL NOS. 22982-23404 OF 2017
(ARISING OUT OF SLP (C) NO.28960-29382 OF 2017)

TRANSFERRED CASE (C) NO.29 OF 2017

TRANSFERRED CASE (C) NO.30 OF 2017

TRANSFERRED CASE (C) NO.31 OF 2017

TRANSFERRED CASE (C) NO.32 OF 2017

TRANSFERRED CASE (C) NO.33 OF 2017

TRANSFERRED CASE (C) NO.34 OF 2017

TRANSFERRED CASE (C) NO.35 OF 2017

TRANSFERRED CASE (C) NO.36 OF 2017

TRANSFERRED CASE (C) NO.38 OF 2017

TRANSFERRED CASE (C) NO.39 OF 2017

TRANSFERRED CASE (C) NO.40 OF 2017

TRANSFERRED CASE (C) NO.41 OF 2017

TRANSFERRED CASE (C) NO.42 OF 2017

TRANSFERRED CASE (C) NO.43 OF 2017

TRANSFERRED CASE (C) NO.44 OF 2017

TRANSFERRED CASE (C) NO.45 OF 2017

TRANSFER PETITION (C) NOS.1176-1182 OF 2017

TRANSFERRED CASE (C) NO.258 OF 2017

TRANSFERRED CASE (C) NO.259 OF 2017

TRANSFERRED CASE (C) NO.260 OF 2017

TRANSFERRED CASE (C) NO.261 OF 2017

TRANSFERRED CASE (C) NO.262 OF 2017

TRANSFERRED CASE (C) NO.263 OF 2017

TRANSFERRED CASE (C) NO.264 OF 2017

TRANSFERRED CASE (C) NO.265 OF 2017

TRANSFERRED CASE (C) NO.266 OF 2017

CIVIL APPEAL NOS. 23405-23472 OF 2017
(ARISING OUT OF SLP (C) NOS. 36044-36111 OF 2017
Diary No.28274 of 2017

TRANSFERRED CASE (C) NOS. 308-317 OF 2017
(ARISING OUT OF T.P. (C) NOS.2108-2117 OF 2017)

J U D G M E N T

R.F. Nariman, J.

1. Leave granted.

2. The present appeals and transfer petitions relate to the interpretation of Section 26A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as "the Drugs Act"). By the impugned judgment of the learned single Judge of the Delhi High Court dated 1.12.2016, the learned single Judge has held that the mandatory condition precedent for the exercise of the power by the Central Government under Section 26A of the Drugs Act is the prior consultation of the Drugs Technical Advisory Board (DTAB) set up under Section 5 of the said Act. It must be stated that the learned single Judge differed from judgments of the Karnataka and Madras High Courts in this regard, wherein two other learned single Judges of two other

High Courts have held that such consultation with the DTAB is not mandatory before exercise of such power under Section 26A. Since we are concerned only with this narrow question that has been decided by the learned single Judge of the Delhi High Court, we are not going into any other contentions that have been raised by learned counsel for the parties.

3. The issue regarding the prevalence of many Fixed Dose Combinations (hereinafter referred to "FDCs") that were flooding the Indian market and had not been tested for efficacy or safety was considered by the Parliamentary Standing Committee on Health and Family Welfare in its 59th Report in May, 2012. The Standing Committee observed that some of the State Licensing Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from the Central Drugs Standard Control Organization (CDSCO). Such FDCs can pose significant risks to persons and need to be withdrawn immediately in that human lives can be at risk. The Committee recommended that a clear and transparent policy may be framed for approving FDCs based on scientific principles, and that, at present,

Section 26A of the Drugs Act is adequate to deal with the problem of FDCs not cleared by the CDSCO. Pursuant to the aforesaid report, the Ministry of Health in October, 2012 issued directions to States and Union Territories under Section 33P of the Drugs Act not to grant licenses to FDCs falling under the definition of "new drugs" and not approved by the Drug Controller General of India (DCG(I)). The DCG(I), in turn, had requested all States/Union Territories Drug Controllers to ask concerned manufacturers in their respective States/Union Territories to prove the safety and efficacy of such FDC licenses issued prior to 1.10.2012, without due approval of the DCG(I), within a period of 18 months, failing which such FDCs would be considered for being prohibited, both qua manufacture and marketing in the country. On 5.7.2013, the DCG(I) vide its communication to the State Drug Controllers asked manufacturers to make applications as per the procedure prescribed within this 18 month period. We have been informed that a large number of applications were received from the manufacturers within the 18 month period for 2911 products, which had to be subjected to examination.

4. With the approval of the Ministry of Health and Family Welfare, the CDSCO constituted 10 different Committees for examination of the said applications which were received on 3.2.2014. As the said Committees could examine only about 295 applications, on 16.9.2014, the Ministry of Health and Family Welfare constituted a Committee under the Chairmanship of Professor C.K. Kokate, Vice Chancellor of KLE University, Belgaum, Karnataka for examining the safety and efficacy as per the following terms of reference:

a. Those FDCs which are considered grossly irrational/unsafe based on pharmacokinetic and pharmacodynamic interaction, dosage compatibilities of FDCs vis-a-vis that of single ingredients present in the FDC and available literature/evidence.

b. Those FDCs which the Committee may consider necessary for further deliberation with any of the 10 Expert Committees already constituted.

c. Those FDCs which are considered as safe and effective based on pharmacokinetic and pharmacodynamic interaction, dosage compatibilities of FDCS vis-a-vis that of single ingredients present in the FDC, available literature/evidence, clinical experience and other data available.

d. Those FDCs which may be considered as rational, based on present data and knowledge available. However, data in post market scenario is

required to be generated within a period of 1 to 2 years to confirm the same.

e. All the FDCs falling, under category “b” above would be referred to the respective Expert Committee out of 10 Expert Committees already constituted.

Composition of Expert Committee for examining the safety & efficacy of Fixed Dose Combinations (FDCs) is as under:

S.No.	Name of Expert	Name & Address of Institutions	Qualification	Status in the Committee
1	Prof. Chandrakant Kokate	Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India.	M. Pharm, Ph.D.	Chairman
2	Dr. C.L. Kaul	Former Director, NIPER, 432, Mahatma Society, Koth Road, Pune-38.	B. Pharm, Ph.D.	Member
3	Prof. Sanjay Singh	Deptt. of Pharmaceutics, IIT, BHU, Varanasi.	M. Pharm, Ph.D.	Member
4	Dr. C.D. Tripathi	Prof. & HOD (Pharmacology), Safdarjung Hospital, New	MD, Pharamacology	Member

		Delhi.		
5	Dr. Bikash Medhi	Deptt. of Pharmacology, PGIMER, Chandigarh.	MD, Pharmacology	Member
6	Dr. Sanjeev Sinha	Prof. (Medicine), AIIMS,New Delhi	MD, Medicine	Member
7	Dr. R.K. Khar	Former Dean & Head, Jamia Hamdard, 403,Lalleshwari Vatika, GH-12, Sector-21D, Faridabad-121001.	M. Pharm, Ph.D.	Co-opted Member

A series of meetings were conducted by the Committee (6 meetings corresponding to 11 days) as well as by a sub-group of the Committee (2 meetings) for examination of these approx. 6320 applications.

5. The first assessment report of the aforesaid Committee was submitted to the Ministry of Health and Family Welfare on 19.1.2015 and was presented before the Ministry on 4.3.2015, wherein the Committee was requested to mention detailed reasons against each FDC considered as “irrational” by the Committee. The Committee did not discuss FDCs already approved by the DCG(I) and FDCs which were licensed pre

21.9.1988 i.e. before the introduction of Schedule Y to the Drugs Act. The Committee stated, “in case the Committee made any comment with respect to the above inadvertently, it shall be treated as not discussed.”

6. On 16.4.2015, a detailed report in this regard was submitted by the Kokate Committee to the Ministry stating the reasons for declaring FDCs as irrational. We have been informed that for the FDCs which were considered as irrational by the Committee, the Committee wrote to various manufacturers/associations calling upon them to submit material to establish the therapeutic justification/rationality of the FDCs. Replies received from such associations were examined by the Expert Committee and final recommendations therein were given only on 10.2.2016. In category A, following the final recommendations of the Expert Committee, the Central Government has banned 344 FDCs. In category B, 944 FDCs needed to be considered/deliberated upon further, which meant that they would be referred to the respective Expert Committees out of the 10 Expert Committees already constituted for further examination. In category C, 1493 FDCs

have been declared “rational” and we are informed that approvals have since been issued by the DCG(I) in respect of these FDCs. In category D, 126 FDCs have to be considered for further generation of data by the prospective applicants. It is only after carrying out of this exercise, that by notifications dated 10.3.2016 issued under Section 26A, the Central Government banned manufacture and sale of 344 FDCs.

7. In March 2016, a large number of writ petitions were filed in the Delhi High Court against the aforesaid notifications. The impugned judgment then followed on 1.12.2016 disposing of 454 petitions, followed by an order dated 21.12.2016, in which the Delhi High Court disposed of 51 further writ petitions in terms of the judgment dated 1.12.2016.

8. Letters Patent Appeals were filed before the Delhi High Court. Meanwhile, the Union of India filed transfer petitions in this Court. This is how these matters have been heard by us in civil appeals arising out of SLPs against the judgment of the single Judge dated 1.12.2016 and in transfer cases in which the

LPAs pending before the Delhi High Court have been transferred to us.

9. Ms. Pinky Anand, learned Additional Solicitor General, took us through various provisions of the Drugs Act, and emphasized that Section 26A does not expressly refer to the DTAB. According to her, a large number of provisions of the Drugs Act expressly refer to the DTAB in various contexts and, therefore, it is not permissible for the Court to read a mandatory requirement of consultation with the DTAB into Section 26A, when such mandatory consultation is present in other provisions, but is conspicuous by its absence in Section 26A. She further went on to state that the provisions of Section 26A are legislative in nature, and ultimately, once the Central Government arrives at a satisfaction based on relevant materials, judicial review of the Central Government decision taken on the basis of Expert Committee reports is extremely limited. She launched an all out attack against the single Judge's judgment and stated that the Madras and Karnataka view, with which the Delhi High Court differed, is the correct view in law. Shri Colin Gonsalves, learned senior counsel,

supported her arguments, and appeared in civil appeal arising out of SLP(C) Nos.10170-10178 of 2017.

10. By way of reply, Shri C.S. Vaidyanathan, learned senior counsel, argued that the impugned single Judge judgment was based on an earlier Division Bench judgment in **E. Merck (India) Ltd. and another** v. **Union of India and another,** (2001) 90 DLT 60, which upheld the constitutional validity of Section 26A on the ground that since the DTAB had to be consulted before passing an order under Section 26A, the said Section would pass constitutional muster. He also referred us to this Court's judgment in **Systopic Laboratories (Pvt) Ltd.** v. **Dr. Prem Gupta & Ors.,** 1994 Supp (1) SCC 160 in furtherance of the same proposition. According to learned counsel, it is clear on a reading of Section 5 of the Drugs Act, that it will apply to both the Central Government and the State Governments on all technical matters that arise out of the administration of the Drugs Act. Since Section 26A deals only with such technical matters, it is obvious that the DTAB's advice has to be taken in every such case as otherwise, if it were open to the Central Government to pick and choose in which case

they would take such advice and which case they would not take such advice, the provision itself would become arbitrary and unreasonable. According to the learned senior counsel, Section 5(5) of the Drugs Act is very important in that it is the DTAB alone who may constitute sub-committees consisting of persons who are not members of the DTAB, who may consider particular matters, thereby making it clear that the DTAB alone can induct experts who are outside Section 5 and not the Central Government. He further referred to the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the "Drugs Rules"), in particular Rules 21, 68A, 122A, 122D and 122DA, to buttress his submission that a detailed filtration process has to be gone through before a drug can be manufactured and put on the market and that the Central Government cannot ban such drug without consulting the technical expert under the Drugs Act namely, the DTAB, that is set up under Section 5. He also argued that Sections 10A and 26A were introduced by way of an amendment in 1982 and this being so, it is clear that it is assumed by Parliament that Section 5 of the Drugs Act will be

read along with both of them so as to make the DTAB a mandatory consultee before action is taken under Section 26A.

11. Shri Vashisht, learned senior counsel appearing for some of the respondents, adverted to Section 5 and stated that it was in two parts, the first being advice to the Central Government on all technical matters arising out of the administration of the Drugs Act and the second (and distinct part) being to carry out other functions assigned to it by the Drugs Act. It is clear, therefore, that in all matters which fall within the first part, the advice of the Board would be mandatory before the Central Government were to take action under Section 26A. He also referred us to Section 7A of the Drugs Act and argued that when the said Drugs Act expressly states that nothing in Section 5 is to apply, it is expressly so stated and that, therefore, the necessary inference would be that Section 5 would apply in all situations other than those covered by Section 7A. He further argued that Section 26A does not have a non obstante clause which puts out of harm's way Section 5, but only a "without prejudice" clause and that too restricted only to Chapter IV, making it clear that Section 26A would have to be

read along with Section 5. According to him, therefore, there is no reason to interfere with the judgment of the Delhi High Court.

12. Dr. A.M. Singhvi, learned senior counsel, argued that on a cursory look at the persons who constitute the DTAB under Section 5, it is an extremely high ranking body which is the technical expert set up by the statute and, therefore, the High Court judgment is right in stating that in all cases arising under Section 26A prior consultation with the DTAB is a must. He argued, in the alternative, that on a purposive and harmonious construction of the Drugs Act as a whole, a middle approach could be that the Central Government may, in emergent situations, not consult the DTAB, but in all other situations should give reasons why the DTAB was not consulted, otherwise the exercise under Section 26A would be found to be constitutionally infirm. According to the learned senior counsel, hearing is mandatory under the said Section and the High Court's reading in the requirement of hearing into the said Section was absolutely correct. He also referred us to judgments dealing with not only how hearing must be added

when it is absent, but to a judgment of this Court which stated that conditional legislation, of which Section 26A is a clear instance, would also require hearing the affected parties.

13. In answer to these submissions, the learned Additional Solicitor General, in rejoinder, went through the 1982 amendment, which introduced Section 26A, and stated that Sections 29 and 35 thereof make it clear that amendments were made in certain Sections with reference to the DTAB under Section 5 and that, therefore, the omission of any reference to the DTAB in Section 26A is deliberate. She also went on to state that Rule 66 of the Drugs Rules, which deals with cancellation of individual licenses and which requires compliance with natural justice, should be contrasted with Section 26A of the Drugs Act which, according to her, is a legislative power as opposed to an administrative power.

14. Having heard learned counsel for the parties, it is first important to set out some of the provisions of the Drugs Act.

> **"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) The Board shall consist of the following members, namely:—

(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 pharmacology 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.

(3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(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) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

6. The Central Drugs Laboratory.—

(1) The Central Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(2) the Central Government may, after consultation with the Board, make rules prescribing—

(a) the functions of the Central Drugs Laboratory;

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(d) the procedure for the submission of the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of Laboratory's reports thereon and the fees payable in respect of such reports;

(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(f) the matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

7. The Drugs Consultative Committee.—

(1) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

7A. Sections 5 and 7 not to apply to Ayurvedic, Siddha or Unani drugs.—

Nothing contained in sections 5 and 7 shall apply to Ayurvedic, Siddha or Unani drugs.

8. Standards of quality.—

(1) For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic compiles with such standard as may be prescribed.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule, for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

10. Prohibition of import of certain drugs or cosmetics.—

From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import—

(a) any drug or cosmetic which is not of standard quality;

(b) any misbranded drug or misbranded or spurious cosmetic;

(bb) any adulterated or spurious drug;

(c) any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(f) any drug or cosmetic the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

12. Power of Central Government to make rules. —

(1) The Central Government may, after consultation with or on the recommendation of the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) xxx xxx xxx

16. Standards of quality.—

(1) For the purposes of this Chapter, the expression “standard quality” means—

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

18. Prohibition of manufacture and sale of certain drugs and cosmetics.—

From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(ii) any cosmetic which is not of a standard quality or is misbranded, adulterated or spurious;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended; and

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

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.

33. Power of Central Government to make rules. —

(1) The Central Government may after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) provide for the establishment of laboratories for testing and analysing drugs or cosmetics;

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether a drug or cosmetic is of standard quality;

(d) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

(dd) prescribe under clause (d) of section 17A the colour or colours which a drug may bear or contain for purposes of colouring;

(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purpose of colouring;

(e) prescribe the forms of licences for the manufacture for sale or for distribution, for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same, the qualifications of such authority and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(ee) prescribe the records, registers or other documents to be kept and maintained under section 18B;

(eea) prescribe the fees for the inspection (for the purposes of grant or renewal of licences) of premises, wherein any drug or cosmetic is being or is proposed to be manufactured;

(eeb) prescribe the manner in which copies are to be certified under sub-section (2A) of section 22;

(f) specify the diseases or ailments which a drug may not purport or claim to prevent, cure or mitigate

and such other effects which a drug may not purport or claim to have;

(g) prescribe the conditions subject to which small quantities of drugs may be manufactured for the purpose of examination, test or analysis;

(h) require the date of manufacture and the date of expiry of potency to be clearly or truly stated on the label or container of any specified drug or class of drugs, and prohibit the sale, stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;

(i) prescribe the conditions to be observed in the packing in bottles, packages, and other containers of drugs or cosmetics, including the use of packing material which comes into direct contact with the drugs and prohibit the sale, stocking or exhibition for sale, or distribution of drugs or cosmetics packed in contravention of such conditions;

(j) regulate the mode of labelling packed drugs or cosmetics, and prescribe the matters which shall or shall not be included in such labels;

(k) prescribe the maximum proportion of any poisonous substance which may be added or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(l) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any patent or proprietary medicine containing such drug;

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(n) prescribe the powers and duties of Inspectors and the qualifications of the authority to which such Inspectors shall be subordinate and specify the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;

(o) prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under section 26 and the fees payable therefor;

(p) specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 31;

(q) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs or cosmetic or class of cosmetics; and

(r) sum which may be specified by the Central Government under section 32-B.

33EED. Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha or Unani drugs in public interest.—

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha or Unani drug is likely to involve any risk to human beings or animals or that any such drug does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the

Official Gazette, prohibit the manufacture, sale or distribution of such drug.

33N. Power of Central Government to make rules.—

(1) The Central Government may, after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic, Siddha or Unani drugs;

(b) prescribe the qualification and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic, Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of Ayurvedic, Siddha or Unani

drugs, and for sale of processed Ayurvedic, Siddha or Unani drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani drugs including the use of packing material which comes into direct contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels;

(g) prescribe the conditions subject to which small quantities of Ayurvedic, Siddha or Unani drugs may be manufactured for the purpose of examination, test or analysis;

(gg) prescribe under clause (d) of section 33EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring;

(gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EEB;

(ggb) prescribe the records, registers or other documents to be kept and maintained under section 33 KB; and

(h) any other matter which is to be or may be prescribed under this Chapter."

15. Having heard learned counsel for the parties, it is clear that Section 26A has been introduced by an amendment in

1982. A bare reading of this provision would show, firstly, that it is without prejudice to any other provision contained in this Chapter (meaning thereby Chapter IV). This expression only means that apart from the Central Government's other powers contained in Chapter IV, Section 26A is an additional power which must be governed by its own terms. Under Section 26A, the Central Government must be "satisfied" that any drug or cosmetic is likely to involve (i) any risk to human beings or families; or (ii) that any drug does not have the therapeutic value claimed or purported to be claimed for it; or (iii) contains ingredients in such quantity for which there is no therapeutic justification. Obviously, the Central Government has to apply its mind to any or all of these three factors which has to be based upon its "satisfaction" as to the existence of any or all of these factors. The power exercised under Section 26A must further be exercised only if it is found necessary or expedient to do so in public interest. When the power is so exercised, it may regulate, restrict or prohibit manufacture, sale or distribution of any drug or cosmetic.

16. Undoubtedly, Section 26A has to be read with the rest of the Drugs Act. So read, it is clear that unlike Section 6(2), Section 8(2), second proviso to Section 10, proviso to Section 12(1), Section 16(2), proviso to Section 18(2), Section 33 and Section 33N, there is no explicit requirement to consult the DTAB set up under Section 5 of the Drugs Act. The question is did the Parliament do so deliberately or is it something that the Court should read into the provision?

17. As has been stated hereinabove, Section 26A was brought in by an amendment in 1982. The amendment specifically made changes in Sections 33 and 33N in which it added the words “on the recommendation of the Board”. From this, it is clear that Parliament in the very Amendment Act which introduced Section 26A made certain changes which involved the DTAB under Section 5 of the said Act. It is clear that the additional power that is given to the Central Government under Section 26A does not refer to and, therefore, mandate any previous consultation with the DTAB. On the contrary, the Central Government may be “satisfied” on any relevant material that a drug is likely to involve any risk to human beings etc. as a

result of which it is necessary in public interest to regulate, restrict or prohibit manufacture, sale or distribution thereof. So long as the Central Government's satisfaction can be said to be based on relevant material, it is not possible to say that not having consulted the DTAB, the power exercised under the said Section would be non est. Take the case of an FDC that is banned in 50 countries of the world owing to the fact that the said FDC involved significant risk to human beings. Assuming that the Central Government is satisfied based on this fact alone, which in turn is based on expert committee reports in various nations which pointed out the deleterious effects of the said drug, can it be said that without consulting the DTAB set up under Section 5, the exercise of the power under Section 26A to prohibit the manufacture or sale or distribution of a drug that is banned in 50 countries would be bad only because the DTAB has not been consulted? The obvious answer is no inasmuch as the Central Government's satisfaction is based upon relevant material, namely, the fact that 50 nations have banned the aforesaid drug, which in turn is based on expert committee reports taken in each of those nations. Take another example.

Suppose the Central Government were to ban an FDC on the ground that, in the recent past, it has been apprised of the fact that the FDCs taken over a short period of time would lead to loss of life, which has come to the notice of the Central Government through reports from various district authorities, in let us say, a majority of districts in which the said FDC has been consumed. Could not the Central Government then base its ban order on material collected from district authorities which state that this particular drug leads to human mortality and ought, therefore, to be prohibited? The obvious answer again is yes for the reason that the Central Government has been satisfied on relevant material that it is necessary in public interest to ban such drug. Examples of this nature can be multiplied to show that the width of the power granted under Section 26A cannot be cut down by artificially cutting down the language of Section 26A.

18. We were referred to a judgment of this Court in **Systopic Laboratories** (supra) at 169. Paragraph 19 of the said judgment reads as follows:-

> "19. Having considered the submissions made by the learned counsel for the petitioners and the learned Additional Solicitor General in this regard, we must express our inability to make an assessment about the relative merits of the various studies and reports which have been placed before us. Such an evaluation is required to be done by the Central Government while exercising its powers under Section 26-A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the DCC."

19. It is clear that a stray sentence in a judgment without a focused argument cannot be considered as the ratio of such a judgment. Also, on a careful reading of the second sentence in paragraph 19, it is clear that all that is stated by this Court is that, while exercising its power under Section 26A of the Drugs Act, the basis of the Central Government's decision must be "expert advice". The sentence then goes on to add that the Drugs Act makes provision for obtaining such advice through the Board and the DCC. According to us, there was no focused argument on whether such advice is or is not mandatory before powers under Section 26A of the Drugs Act can be exercised, and merely reading a stray sentence in this judgment does not lead to such a conclusion. Equally, the single Judge's reliance upon a Division Bench judgment contained in **E. Merck** (supra),

where, in holding Section 26A to be constitutional, the Court stated:

> "Before the Government records its satisfaction to prohibit the manufacture, sale, distribution etc. of a particular drug, opinion of the DTAB and/or Drugs Consultative Committee is obtained."

This is an equally stray sentence and what has been stated with respect to **Systopic Laboratories** (supra), applies equally to this sentence.

20. We have now to consider certain other arguments made on behalf of the respondents. One argument was that Section 5 is in two parts and that the first part necessarily applies to all technical matters that arise out of the administration of the Drugs Act, and that, therefore, the Central Government is bound to take the advice of the DTAB in all such matters. We must first advert to the fact that the DTAB is only an advisory body. No doubt, it would be desirable for the Central Government to take its advice on technical matters arising out of the administration of the Drugs Act, but this does not lead to the conclusion that if such advice is not taken power under Section 26A cannot be exercised. Indeed, the Central

Government's satisfaction may be based on a number of factors, one of which may be advice tendered to it by the DTAB under Section 5. There is no warrant to read Section 26A to constrict the wide powers granted to the Central Government by a so-called harmonious construction of the statute. Another argument made is that Section 5 makes it clear that the DTAB alone can constitute sub-committees which may have persons who are not members of the Board on them. We are afraid that this again does not lead us very far. It is clear that the reason for Section 5(5) is completely different. Sub-committees may be appointed for such periods not exceeding three years or temporarily for the consideration of particular matters. Such sub-committees may be set up in the wisdom of the DTAB for short periods of time or temporarily to consider certain matters and make reports which the DTAB may then utilize. This is a power of the DTAB which can be exercised when the DTAB deems it desirable. From this power, it cannot be inferred, as a matter of logic, that since Section 5(5) permits persons who are not members of the board to sit on sub-committees, the Central Government may not, under Section 26A, refer to any persons

other than those who are board members. This argument, therefore, is also rejected.

21. Yet another argument has been made that since Section 10A and 26A were brought in together by an Amendment Act in 1982, it must, therefore, somehow be assumed that the Amendment Act necessarily included a mandatory consultation with the DTAB set up under Section 5. We have already pointed out how the very amendment Act of 1982 also amended Sections 33 and 33N by referring to the DTAB and that, therefore, it is obvious that the omission of any reference to the DTAB under Sections 10A and 26A cannot but be said to be deliberate. This argument also need not detain us further.

22. A negative argument was made stating that Section 7A of the Drugs Act makes it clear that Section 5 will not apply to Ayurvedic, Siddha or Unani drugs and that, therefore, it will apply to all other drugs. The reason for Section 7A is again something very different from what has been argued. It must first be pointed out that under Chapter IVA, which is a separate Chapter introduced by Act 13 of 1964, Ayurvedic, Siddha and

Unani drugs are completely separately dealt with. Indeed, Section 33A, which must be read with Section 7A, expressly provides that save as provided in this Drugs Act, nothing contained in this Chapter, i.e. Chapter IV, shall apply to Ayurvedic, Siddha or Unani drugs. Chapter IVA consists of a separate and distinct drill to be followed in the case of Ayurvedic, Siddha and Unani drugs. Under Section 33C, there is a separate technical advisory board for Ayurvedic and Unani drugs and a separate consultative committee for Ayurvedic, Siddha and Unani drugs (see Section 33D). When Section 7A says that nothing in section 5 shall apply to Ayurvedic, Siddha or Unani drugs, all that it affirms is that the DTAB set up under Section 5 will apply to all drugs except Ayurvedic, Siddha or Unani medicines. The Latin maxim "expressio unius est exclusio alterius" cannot apply, as has been held in **State of Karnataka** v **Union of India & Ors.**, (1977) 4 SCC 608 at 662, making it clear that the said maxim should be very carefully applied and when misapplied would turn out to be a "dangerous master" as opposed to a "useful servant". This has also been held in **Assistant Collector of Central Excise, Calcutta**

Division v. **National Tobacco Co. of India Ltd.**, (1972) 2 SCC 560 at 575 as follows:

> "The High Court's view was based on an application of the rule of construction that where a mode of performing a duty is laid down by law it must be performed in that mode or not at all. This rule flows from the maxim: "*Expressio unius ast exclusio alterius*". But, as was pointed out by Wills, J., in *Colguoboun* v. *Brooks* [(1888) 21 QBD 52, 62] this maxim "is often a valuable servant, but a dangerous master….". The rule is subservient to the basic principle that Courts must endeavour to ascertain the legislative intent and purpose, and then adopt a rule of construction which effectuates rather than one that may defeat these. "

This argument, therefore, also need not detain us.

23. It was also argued that Section 26A had no non obstante clause to keep Section 5 out of harm's way. On our construction of Section 26A, it is clear that no such non obstante clause was necessary in that the width of the expression "is satisfied" contained in Section 26A cannot be cut down by reference to Section 5. As has been stated by us hereinabove, the expression "without prejudice" makes it clear that Section 26A is an additional power given to the Central Government which must be exercised on its own terms.

24. An argument was made that unless the provisions of Section 5 requiring consultation with the DTAB are read into Section 26A, the said Section would be arbitrary. In our opinion, there are sufficient indicators in the Section to eschew any ground of arbitrariness. The power can only be exercised based on satisfaction of material that is relevant to form an opinion that the drug in question falls within any of the three categories outlined by the Section and that, further, it is necessary or expedient to either regulate, restrict or prohibit manufacture, sale or distribution of the said drug in public interest. Indeed, this is made explicit in Section 33 EED of the Drugs Act, wherein a similar power is given to the Central Government qua Ayurvedic, Siddha or Unani drugs, where the Section states:

> "… the Central Government is satisfied on the basis of any evidence or other material available before it that …"

25. If the power under Section 26A is exercised on the basis of irrelevant material or on the basis of no material, the satisfaction itself that is contemplated by Section 26A would not

be there and the exercise of the power would be struck down on this ground. Further, it is argued that the provision may be read down to make it constitutionally valid, but in so doing, words cannot be added as a matter of constitutional doctrine.

26. In **Cellular Operators Association of India and others** v. **Telecom Regulatory Authority of India and others,** (2016) 7 SCC 703 at 740-741, this Court held as under:

> "50. But it was said that the aforesaid Regulation should be read down to mean that it would apply only when the fault is that of the service provider. We are afraid that such a course is not open to us in law, for it is well settled that the doctrine of reading down would apply only when general words used in a statute or regulation can be confined in a particular manner so as not to infringe a constitutional right. This was best exemplified in one of the earliest judgments dealing with the doctrine of reading down, namely, the judgment of the Federal Court in *Hindu Women's Rights to Property Act, 1937, In re* [*Hindu Women's Rights to Property Act, 1937, In re*, AIR 1941 FC 72]. In that judgment, the word "property" in Section 3 of the Hindu Women's Rights to Property Act was read down so as not to include agricultural land, which would be outside the Central Legislature's powers under the Government of India Act, 1935. This is done because it is presumed that the legislature did not intend to transgress constitutional limitations. While so reading down the word "property", the Federal Court held:

> "… If the restriction of the general words to purposes within the power of the legislature would be to leave an Act with nothing or next to nothing in it, *or an Act different in kind, and not merely in degree*, from an Act in which the general words were given the wider meaning, then it is plain that the Act as a whole must be held invalid, because in such circumstances it is impossible to assert with any confidence that the legislature intended the general words which it has used to be construed only in the narrower sense: *Owners of SS Kalibia* v. *Wilson* [(1910) 11 CLR 689 (Aust)], *Vacuum Oil Co. Pty. Ltd.* v. *Queensland* [(1934) 51 CLR 677 (Aust)], *R*. v. *Commonwealth Court of Conciliation and Arbitration, ex p Whybrow & Co.* [(1910) 11 CLR 1 (Aust)] and *British Imperial Oil Co. Ltd.* v. *Federal Commr. of Taxation* [(1925) 35 CLR 422 (Aust)]."

51. This judgment was followed by a Constitution Bench of this Court in *DTC* v. *Mazdoor Congress* [1991 Supp (1) SCC 600 : 1991 SCC (L&S) 1213]. In that case, a question arose as to whether a particular regulation which conferred power on an authority to terminate the services of a permanent and confirmed employee by issuing a notice terminating his services, or by making payment in lieu of such notice without assigning any reasons and without any opportunity of hearing to the employee, could be said to be violative of the appellants' fundamental rights. Four of the learned Judges who heard the case, the Chief Justice alone dissenting on this aspect, decided that the regulation cannot be read down, and must, therefore, be held to be unconstitutional. In the lead

judgment on this aspect by Sawant, J., this Court stated: (SCC pp. 728-29, para 255)

> "255. It is thus clear that the doctrine of reading down or of recasting the statute can be applied in limited situations. It is essentially used, firstly, for saving a statute from being struck down on account of its unconstitutionality. It is an extension of the principle that when two interpretations are possible — one rendering it constitutional and the other making it unconstitutional, the former should be preferred. The unconstitutionality may spring from either the incompetence of the legislature to enact the statute or from its violation of any of the provisions of the Constitution. The second situation which summons its aid is where the provisions of the statute are vague and ambiguous and it is possible to gather the intentions of the legislature from the object of the statute, the context in which the provision occurs and the purpose for which it is made. *However, when the provision is cast in a definite and unambiguous language and its intention is clear, it is not permissible either to mend or bend it even if such recasting is in accord with good reason and conscience.* In such circumstances, it is not possible for the court to remake the statute. Its only duty is to strike it down and leave it to the legislature if it so desires, to amend it. What is further, if the remaking of the statute by the courts is to lead to its distortion that course is to be scrupulously avoided. One of the situations further where the

> doctrine can never be called into play is where the statute requires extensive additions and deletions. Not only it is no part of the court's duty to undertake such exercise, but it is beyond its jurisdiction to do so."
>
> (emphasis supplied)
>
> 52. Applying the aforesaid test to the impugned Regulation, it is clear that the language of the Regulation is definite and unambiguous — every service provider has to credit the account of the calling consumer by one rupee for every single call drop which occurs within its network. The Explanatory Memorandum to the aforesaid Regulation further makes it clear, in Para 19 thereof, that the Authority has come to the conclusion that call drops are instances of deficiency in service delivery on the part of the service provider. It is thus unambiguously clear that the impugned Regulation is based on the fact that the service provider is alone at fault and must pay for that fault. In these circumstances, to read a proviso into the Regulation that it will not apply to consumers who are at fault themselves is not to restrict general words to a particular meaning, but to add something to the provision which does not exist, which would be nothing short of the court itself legislating. For this reason, it is not possible to accept the learned Attorney General's contention that the impugned Regulation be read down in the manner suggested by him."

27. Also, as a matter of statutory interpretation, words can only be added if the literal interpretation of the Section leads to an absurd result. As has been stated by us, the construction of

Section 26A on a literal reading thereof does not lead to any such result. Dr. Singhvi's argument to read in words to save Section 26A must, therefore, be rejected.

28. We may also mention that the Madras High Court in its judgment in **Macleods Pharmaceuticals Limited** v. **Union of India & Ors.**, Writ Petition Nos.21933 and 25442 of 2011, specifically held as under:

> "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."

29. To similar effect is the judgment of a single Judge of the Karnataka High Court in **Lundbeck India Pvt. Ltd.** v **Union of India,** (2014) 5 Kant LJ 440.

30. We approve of these two judgments as having laid down the correct law on the construction of Section 26A of the Drugs Act.

31. Though arguments have been made as to whether Section 26A is legislative in nature and therefore excludes natural justice, we do not propose to go into the same inasmuch as since the learned single Judge's judgment is being set aside on one point and one point alone. In this view of the matter, we are of the opinion that the impugned judgment dated 1.12.2016 deserves to be set aside.

32. On the facts of these cases, a suggested course of action was stated by learned counsel appearing on behalf of the petitioners/appellants. This course is that instead of now remitting the matter back to the Delhi High Court for an adjudication on the other points raised in the writ petitions, the case of 344 FDCs that have been banned, plus another 5 FDCs that have been banned, which comes to 349 FDCs, (barring 15 FDCs that are pre 1988 and 17 FDCs which have DCG(I) approval) pursuant to the Kokate Committee report, by notifications of the Central Government under Section 26A of the Drugs Act, should be sent to the DTAB, constituted under Section 5 of the Drugs Act, so that it can examine each of these cases and ultimately send a report to the Central Government. We reiterate that only on the peculiar facts of these cases, we think that such a course commends itself to us, which would obviate further litigation and finally set at rest all other contentions raised by the petitioners. We say so because we find that the Kokate Committee did deliberate on the 344 FDCs plus 5 FDCs and did come to a conclusion that the aforesaid FDCs be banned, but we are not clear as to what exactly the

reasons for such conclusions are, and whether it was necessary in the public interest to take the extreme step of prohibiting such FDCs, instead of restricting or regulating their manufacture and supply. In order that an analysis be made in greater depth, we, therefore, feel that these cases should go to the DTAB and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases. It is important, however, that the DTAB/Sub-Committee appointed for this purpose will not only hear the petitioners/appellants before us, but that they also hear submissions from the All India Drugs Action Network. The DTAB/Sub-Committee set up for this purpose will deliberate on the parameters set out in Section 26A of the Drugs Act, as follows.

33. First and foremost in each case, the DTAB/Sub-Committee appointed by it must satisfy itself that the use of the Fixed Dose Combinations (FDC) in question is likely to involve any one of the aforesaid three things:

(a) that they are likely to involve any risk to human beings or animals; or

(b) that the said FDCs do not have the therapeutic value claimed or purported to be claimed for them; or

(c) that such FDCs contain ingredients and in such quantity for which there is no therapeutic justification.

34. The DTAB/Sub-Committee must also apply its mind as to whether it is then necessary or expedient, in the larger public interest, to regulate, restrict or prohibit the manufacture, sale or distribution of such FDCs. In short, the DTAB/Sub-Committee must clearly indicate in its report:

(1) as to why, according to it, any one of the three factors indicated above is attracted;

(2) post such satisfaction, that in the larger public interest, it is necessary or expedient to (i) regulate, (ii) restrict, or (iii) prohibit the manufacture, sale or distribution of such FDCs.

35. The DTAB/Sub-Committee must also indicate in its report as to why, in case it prohibits a particular FDC, restriction or regulation is not sufficient to control the manufacture and use of the FDC. We request the DTAB/Sub-Committee to be set up for this purpose to afford the necessary hearing to all

concerned, and thereafter submit a consolidated report, insofar as these FDCs are concerned, to the Central Government within a period of six months from the date on which this judgment is received by the DTAB. We may also indicate that the Central Government, thereafter, must have due regard to the report of the DTAB and to any other relevant information, and ultimately apply its mind to the parameters contained in Section 26A of the Drugs Act and, accordingly, either maintain the notifications already issued, or modify/substitute them or withdraw them.

36. With these directions given on the peculiar facts and circumstances of these cases, the appeals are disposed of.

37. Insofar as the drugs that have been banned and which were manufactured pre 21st September, 1988, a list of 15 such drugs has been given to us by Mr. Kapil Sibal, learned senior counsel for the respondents. We set aside the Central Government notifications banning them as these cases were never meant to be referred to the Kokate Committee. It will be open, however, for the Central Government, if it so chooses, de

novo, to carry out an inquiry as to whether such drugs should be the subject matter of a notification under Section 26A of the Drugs Act.

38. Insofar as the list of 17 cases handed over by Shri Sibal, in which DCG(I) approvals have allegedly been granted, we are of the view that since the Parliamentary Standing Committee itself refers to DCG(I) approvals and the manner in which they were granted, we do not accede to Mr. Sibal's request that these 17 cases be kept outside the purview of the fresh look that has to be given by the DTAB/Sub-Committee in these cases.

39. Insofar as the status quo, obtaining as on today, is concerned, that will continue in all cases (including the 5 FDCs which are not the subject matter of stay orders already made) until the Central Government issues fresh notifications in this behalf.

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40. Mr. Gopal Subramanium, learned senior counsel appearing on behalf of the original petitioners in these cases, stated that these cases have been transferred to this Court from the Madras High Court. A Section 33 ban, which was imposed on 294 FDCs in these cases, has been stayed by the Madras High Court, and the very exercise that we have proposed in the Delhi cases has apparently been carried out in this group of cases. A report of the expert committee of the DTAB to review the rationality and safety of 294 FDCs is taken on record. The report indicates that 42 FDCs reportedly were repeated or duplicate; 44 were already prohibited for manufacture in the country; 83 were considered rational; 56 were considered not rational; 49 required further generation of data; 17 were considered inadequate so far as rationality, safety and efficacy is concerned; and 3 other cases were sent for further examination by an expert committee constituted by the Ministry of Health and Family Welfare. The DTAB after review of the report and deliberations recommended that the FDC Ofloxacin and Prednisolone at serial number 75 under the category of GI in Annexure C does not appear to be rational

and should be re-examined. The list of the drugs mentioned in Annexure D are required to be prohibited/withdrawn from the market as these are not rational. Considering that an expert body has already deliberated upon and decided these cases, we accept the report, and accordingly dispose of these petitions in accordance therewith.

…….J.
(R.F. Nariman)

…….J.
(Sanjay Kishan Kaul)

New Delhi;
December 15, 2017.