* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% **Date of decision: 1st December, 2016**.

\+ **W.P.(C) No.2212/2016**

PFIZER LIMITED & ANR ..... Petitioners

Versus

UNION OF INDIA & ANR ..... Respondents

AND

453 OTHER PETITIONS AS PER SCHEDULE

Counsels for the petitioners:-
Mr. Kapil Sibal, Mr. P. Chidambaram, Mr. Ashok Desai, Mr. C.S. Vaidynathan, Mr. Parag P. Tripathi, Mr. S. Ganesh, Mr. A.S. Chandhiok, Mr. Arvind K. Nigam, Mr. Rajiv Nayar, Mr. Sandeep Sethi, Mr. Gopal Jain, Mr. Siddharth Luthra, , Mr. Rajiv Virmani, Ms. Prathiba M. Singh, Mr. Abhinav Vashisht, Mr. Ashwini Mata, Mr. Suddhanshu Batra, Mr. J.P. Sengh, Mr. Amit Sibal, Mr. Dayan Krishnan, Ms. Rekha Palli, Senior Advocates.

Assisted By

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Mr. R. Jawaharlal, Mr. S. Bawa, Mr. Shyamal Anand, Mr. Abdullah Hussain, Mr. Rudresh Singh, Mr. Arjun Nihal Singh, Mr. Sanjeev Singh,

Mr. Vineet Malhotra, Mr. Shubendu Kaushik, Mr. Neeraj Grover, Mr. Aditya Singh, Mr. Krishnendu Datta, Ms. Sanjana Saddy, Ms. Shruti Munjal, Mr. Udit Chauhan, Mr. Hemant Daswani, Ms. Gurkamal Hora Arora, Mr. Binoy Kumar, Mr. Utkarsh, Mr. Anshu, Ms. Kripa Pandit, Mr. Vikas Mehta, Mr. Rajat Sehgal, Mr. Shivam Singh, Mr. Aditya Raina, Mr. Rakesh Kumar, Ms. Preeti Kashyap, Mr. Aditya Nayyar, Mr. Rajiv Bajaj,

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CORAM:
HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

1. These 454 petitions impugn the 344 Notifications dated 10th March, 2016 of the Government of India, all in exercise of power under Section 26A of the Drugs and Cosmetics Act, 1940 (Drugs Act) in respect of 344 Fixed Dose Combination (FDC) Drugs and seek to prohibit the respondents Union

of India and the Drugs Controller General (India) (Drugs Controller) from giving effect thereto or from prohibiting the manufacture, distribution and sale in the territory of India of drugs based on the said FDCs (At one stage of the hearing the learned ASG appearing for the respondents informed that the challenge in all these petitions is to 100 odd FDCs only and there is no challenge to the other of the 344 FDCs subject matter of these Notifications but it was informed that W.P.(C) No.2500/2016 is preferred by the Federation of Pharma Enterpreneurs and impugns all the 344 Notifications).

2. W.P.(C) No.2212/2016 impugning Notification No.SO-909 (E) with respect to FDC of Chlopheniramine Maleate + Codeine Syrup came up before this Court first on 14th March, 2016 when the counsels for the respondents appeared on advance notice. Notice of the petition was issued and in view of the fact that the drug Corex with the said FDC had been marketed by the petitioner therein for 25 years prior thereto and that the impugned Notification, save for generally stating that the use of the said drug was "likely to involve risk to human beings" did not disclose any grave urgency, the effect of the Notification was stayed and the respondents restrained from taking any coercive steps against the petitioners or its stockists / agents pursuant to the said Notification.

3. Thereafter, this Court was flooded with other petitions aforesaid. In all, 458 petitions were received and of which four were withdrawn/disposed of, either on realising that the drug, which at the time of filing of the petition was wrongly considered as covered by the Notification was not so covered or on clarification of the counsels for the respondents of the drug subject matter of those petitions being not covered by the Notification. Now, 454 petitions aforesaid survive. Though a large number of counsels as listed above appeared in the petitions but the nature of the challenge being the same, arguments were addressed with reference to the pleadings in W.P.(C) No.2212/2016. Needless to state that the same interim order as granted in W.P.(C) No.2212/2016 followed in other petitions as well. For the sake of expediency, it was directed that pleadings in all the petitions need not be completed and that all the petitions will be considered and decided together. This judgment thus, besides W.P.(C) No.2212/2016, decides the other 453 petitions as well, list whereof is given in Schedule to this judgment.

4. On the request of the learned ASG appearing for the respondents, he was granted the right of audience first for about one hour on 28th March, 2016, when hearing began. The counsels for the petitioners were heard on 28th March, 29th March, 30th March & 31st March, 2016. The learned ASG

commenced his arguments on 31st March, 2016 and continued on 4th April, 6th April, 18th April, 28th April, 5th May, & 12th May, 2016, on which date, the counsel appearing for the applicant All India Drug Action Network seeking impleadment was also heard. The counsels for the petitioners addressed arguments in rejoinder on 19th May, 2016. On 26th May, 2016, besides hearing counsels for the petitioners in rejoinder, the counsels for Veterans' Forum for Transparency in Public Life and one Mr. Dhirendra Singh, both also seeking intervention, were heard. Arguments of the counsel for the petitioners continued on 27th May, 30th May, 31st May & 2nd June, 2016, when the learned ASG was also further heard and orders reserved.

5. The Notification impugned in W.P.(C) No.2212/2016 aforesaid is as under:

> *"**NOTIFICATION***
>
> *New Delhi, the 10th March, 2016*
>
> *S.O. 909(E)—Whereas, the Central Government is satisfied that the use of the drug **fixed dose combination of Chlopheniramine Maleate + Codeine Syrup** is likely to involve risk to human beings whereas safer alternatives to the said drug are available;*
>
> *And whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central*

Government that the said drug is found to have no therapeutic justification;

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country;

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug ***fixed dose combination of Chlopheniramine Maleate + Codeine Syrup*** *with immediate effect.*

[F.No.X-11035/53/2014-DFQC]

K.L. SHARMA, Jt. Secy."

The language of Notifications impugned in other petitions is identical.

6. It is the case of the petitioner in W.P.(C) No.2212/2016:

(i) that Corex is a combination drug sold in India since the year 1989, though its composition has been revised / modified from time to time with the approval of the Drugs Controller; the composition was so last changed in 1995;

(ii) that Corex falls under Schedule H-1 of the Drugs and Cosmetics Rules, 1945 (Drugs Rules) and is sold to end user only when prescribed by medical practitioners and administered under their supervision and guidance;

(iii) that similar pharmacological composition is being sold in United States of America (USA), Europe, United Kingdom (UK) and Australia;

(iv) that Corex is a combination of (1) Chlorpheniramine Maleate IP; (2) Codeine Phosphate IP; and (3) Carmoisine and Sunset Yellow CPF as colorants;

(v) that the presence of Chlorpheniramine Maleate in the subject drug is necessary since it is an antihistamine for relieving histamine-induced allergic edema or respiratory mucosa;

(vi) that the presence of codeine phosphate in the subject drug is necessary since it is an antitussive;

(vii) that the manufacture of Corex without either of the ingredients would be meaningless as it would lose its efficacy;

(viii) that Chlorpheniramine Maleate prevents the nasal and bronchial secretions which would irritate the glands in the throat thereby leading to dry cough;

(ix) that codeine phosphate suppresses the glands i.e. reduces the cough reflexes;

(x) that the combination works effectively as both the ingredients compliment each other; without the secretions being prevented, it would be difficult to suppress the cough reflexes and vice-versa;

(xi) that the packaging of Corex contains warning in bold to the effect that it is to be sold by retail on prescription of registered medical practitioner and that it is dangerous to consume the same except under medical supervision;

(xii) that no show cause notice or notice of any other nature was issued to the petitioner prior to the impugned Notification and no opportunity of hearing was given;

(xiii) that though the impugned Notification claims that "safer alternatives are available" but whether the same are efficacious or not, requires consultation and debate; moreover, no such alternatives have been disclosed in the Notification;

(xiv) that even if safer alternatives are available, reasonable time frame is required to adopt the same;

(xv) that such immediate ban on Corex and other similar combinations which had been in market for over 25 years is illegal;

(xvi) that the Notification does not refer to any scientifically proven evidence with regard to the risk to human beings caused by combination / subject drug Corex;

(xvii) that the procedure prescribed in the Drugs Act and the Drugs Rules has not been followed;

(xviii) that the respondents have acted on the *ex-parte* findings of the Expert Committee constituted without any reasonable justification;

(xix) that all the 344 Notifications issued on the same day have the same language, showing a complete non-application of mind;

(xx) that no scientific evidence to disprove the therapeutic justification of any of the ingredients of the drug Corex has been cited.

7. A counter affidavit dated 19th March, 2016 was filed by the Deputy Secretary to the Government of India pleading:

(a) that a list of Fixed Dose Combinations (FDCs) as approved by the Ministry of Health and Family Welfare, Government of India (Ministry) was published on the website of Central Drugs Standard Control Organisation (CDSCO) in the year 2013 in which the FDC of Chlorpheniramine Maleate + Codeine Syrup manufactured by the petitioner was not mentioned as an approved drug;

(b) that the aforesaid list was appended with a footnote mentioning that if any inconsistency is observed, the same may be brought to the notice of the Drugs Controller for necessary action;

(c) that the petitioner never disclosed that it holds some kind of 'No Objection Certificate' (NOC) from the Drugs Controller for this combination;

(d) that the petitioner had never formally approached CDSCO apprising of the status of its approval;

(e) that it came to the knowledge of CDSCO through National Pharmaceutical Pricing Authority (NPPA) in some other matter that the product Corex is having some NOC dated 10th March, 1995 from the Drugs Controller; accordingly the status of approval was uploaded on the CDSCO website on 7th May, 2015;

(f) that the Drugs Act had been enacted with the objective of assuring the rationality, safety and efficacy of drugs marketed in the country with a view to protect public health;

(g) that the combination of two or more drugs i.e. FDC, for the first time fell under the definition of a 'new drug';

(h) that the requirements for import, manufacture of new drug including FDCs was introduced in Drugs Rules with effect from 21st September, 1988 by introducing Rules 122A, 122B, 122D & 122E and Schedule Y which required that the manufacturers of FDCs falling under the definition of new drug shall require the permission from Drugs Controller;

(i) that FDC is a new drug as defined under Rule 122E which specifies the procedure to be followed for obtaining manufacturing permission / marketing authorisation;

(j) that the said procedure involves examination and experimentation including clinical and non-clinical studies of the molecule and the

applicant is required to establish the rationality, safety and efficacy of the FDC;

(k) that the Competent Authority for the grant of approval for import, manufacturing and marketing of any new drug in the country is the Licensing Authority as defined in Rule 21(b) of the Drugs Rules, i.e. the Drugs Controller;

(l) that a product which falls under the definition of a new drug but is wrongly licensed by any State Licensing Authority (SLA) without any approval of the Drugs Controller cannot be the basis to assume that the product is rational, safe and efficacious;

(m) that the permission from the Drugs Controller is pre-requisite before new drug is licensed by the SLA for manufacture for sale or sale in the country;

(n) that however the manufacturers, from September, 1988 till 1st October, 2012, were obtaining the licenses for manufacturing such FDCs which fall under the ambit of new drug, without due approval of the Drugs Controller;

(o) that in order to address this issue, the Ministry had issued repeated statutory directions under Section 33P of the Drugs Act to the State Governments to instruct their respective Drug Licensing Authorities to refrain from granting licences for manufacture of new drugs and FDCs covered under the definition of new drug without the approval of the Drugs Controller;

(p) that the last such direction was issued on 1st October, 2012;

(q) that the practice of obtaining licences from SLAs for FDCs which had never been evaluated for their safety and efficacy prior to their licence had continued unabated;

(r) that earlier, in 2007, the Drugs Controller had received complaints from consumer associations regarding the rationality of certain FDCs marketed in the country;

(s) that as a part of follow up action on the complaints, the Drugs Controller prepared a list of 294 FDCs and directions were issued to the State Drugs Controllers to withdraw 294 FDCs which were licensed without approval of the Drugs Controller;

(t) that however the manufacturers association obtained a stay from the Madras High Court and the matter is still sub-judice;

(u) that taking cognizance of the situation, the Parliamentary Standing Committee on Health and Family Welfare in its 59th report on the functioning of CDSCO also took notice of the SLAs having issued manufacturing licences for a large number of FDCs without prior clearance from CDSCO and resulting in the availability of many FDCs in the market which had not been tested for safety and efficacy, putting patients at risk;

(v) that the Parliamentary Standing Committee also observed that Section 26A of the Drugs Act is adequate to deal with the problem of FDCs not cleared by CDSCO;

(w) that pursuant to the aforesaid report, the Ministry issued directions aforesaid on 1st October, 2012 followed by letters dated 15th, January 2013 and 5th July, 2013 to the State Drugs Controllers to ask the manufacturers to make their applications to the Drugs Controller;

(x) that in response thereto, CDSCO received a large number of applications from the manufacturers;

(y) that with the approval of Ministry, CDSCO, on 3rd February, 2014, constituted ten different committees for examination of the said applications received by it;

(z) that the meetings of those committees took place on various dates and discussed the FDCs;

(aa) that the said ten committees examined only limited number of applications out of the large number received;

(bb) that therefore in public interest, in order to examine the remaining applications in a timely manner, the Ministry vide order dated 16th September, 2014 constituted a committee under the Chairmanship of Professor C.K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka for examining the safety and efficacy "of these FDCs";'

(cc) that the terms of reference of the Kokate Committee were as under:

"a. Those FDCs which are considered grossly irrational/unsafe based on pharmacokinetic and pharmacodynamic interation, 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 interation, 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."

(dd) that series of meetings were conducted by the Kokate Committee for examination of these FDCs;

(ee) that the first assessment report of the Kokate Committee was submitted to the Ministry on 19th January, 2014 and on examination whereof the Ministry requested the Kokate Committee to make detailed presentation;

(ff) that accordingly, the Chairman of the Kokate Committee along with the members presented the report before the Ministry on 4th March, 2015, when the Kokate Committee was requested to further examine and elaborate the scientific reasons for each

FDC considered as irrational by the Kokate Committee and submit report;

(gg) that further meetings of Kokate Committee took place on 7th April, 2015 and 8th April, 2015 and detailed report specifically in this regard was submitted to the Ministry on 16th April, 2015;

(hh) that the Government, after examination of the matter, accepted the recommendations of Kokate Committee and based on those recommendations, in case of FDCs declared as irrational, it was decided to issue show cause notices and give opportunity "to the applicants, who had applied for such FDCs to CDSCO";

(ii) that accordingly, show cause notices were issued and a period of thirty days was given to respond and which was subsequently extended by ninety days;

(jj) that the replies received were examined by the Kokate Committee and further recommendations were given by the Kokate Committee on 10th February, 2016, after thorough examination of all replies and data with respect to each composition of FDC;

(kk) that the Kokate Committee also invited one expert of Internal Medicine in all these meetings and one relevant subject expert nominated by the Director General Health Services, wherever necessary;

(ll) that the Government had thus made elaborate efforts to ensure that all facets of the matter got duly examined and no injustice is done to anyone and that the safety of patients is not compromised;

(mm) that in the process, sufficient notice and opportunity has been given to all concerned to present their case;

(nn) that in cases where the composition of the FDC was found irrational even after second examination including of the replies from the applicants, the Government had no option but to prohibit them and hence the impugned Notifications under Section 26A of the Drugs Act were issued;

(oo) that in compliance with the letter dated 15th January, 2013 supra, applications were also received in respect of FDC of Chlorpheniramine Maleate + Codeine Syrup from various manufacturers except from the petitioner in W.P.(C) No.2212/2016;

(pp) that even when show cause notices were issued to the applicants of this very FDC, the petitioner in W.P.(C) No.2212/2016 chose not to submit any representation to the office of the Drugs Controller for proving the safety and efficacy of its drug Corex;

(qq) that the petitioner in W.P.(C) No.2212/2016 was in full knowledge of the fact that the safety and efficacy of this particular FDC was under examination;

(rr) that though Corex has some kind of NOC dated 10th March, 1995 from the Drugs Controller and for reason whereof the approval status thereof was uploaded on the website on 7th May, 2015 but the Kokate Committee examined this FDC in the context of other applicants who had applied to Drugs Controller considering this as an unproved FDC;

(ss) that even if an approval to this FDC was granted in the year 1995, it was done on the basis of literature and knowledge available at that point of time and the same does not bar re-examining the FDC in the current scenario in the light of latest scientific knowledge and information and which has been done by the Kokate Committee which has found the FDC of Corex to be irrational and recommended its ban for the following reasons:

- *"Pharmacodynamically irrelevant and pharmacokinetic mismatch. Also it has abuse potential.*
- *Dosing schedule is incompatible.*
- *Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interfere with the reflexes.*
- *There is a high risk of abuse potential of this formulation in Indian scenario."*

(tt) that Corex Syrup available in India is not approved in USA, UK, Australia or any other country;

(uu) that the combinations referred to by the petitioner are mostly in 'tablet' form and containing Chlorpheniramine Maleate in sustained release form and not as plain syrup. Codeine and Chlorpheniramine Maleate when combined as such in a syrup form makes its dosing schedule incompatible as codeine has a half life of 2.9 hours, while half life of Chlorpheniramine Maleate varies from 12 to 43 hours;

(vv) that both these ingredients when mixed together in a syrup form will aggravate the adverse effects of sedation and drowsiness and also will interfere with the reflexes which is harmful for children and geriatric patients;

(ww) that since the petitioner in W.P.(C) No.2212/2016 did not come out to show that it has NOC from the Drugs Controller, despite having knowledge that the safety and efficacy of its FDC was being examined, there was no occasion to issue any notice to the petitioner and which notice was issued to other applicants;

(xx) that the letter dated 15th January, 2013 supra was put on the official website of CDSCO giving an opportunity to all the manufacturers to apply to CDSCO for proving safety and efficacy;

(yy) that the matter was also discussed on 24th July, 2015, at the 48th meeting of the Drugs Consultative Committee (DCC) constituted under Section 7 of the Drugs Act and which comprises of members from all the State Drug Control Departments and DCC recommended that the ban on manufacture and sale of Phensedyl and preparations

having similar composition may be considered by CDSCO in view of its rampant misuse and illegal export to neighbouring countries;

(zz) that the reference by the petitioner to the use of individual ingredients present in their drug is misconceived, as the prohibition is on the combination and not on individual drugs present in the FDC;

(aaa) that there is a pharmacokinetic mismatch in the individual drugs and which aggravates the adverse effect of sedation and drowsiness and interferes with the reflexes;

(bbb) that in the Indian scenario, there is also a high risk of abuse potential;

(ccc) that Section 26A of the Drugs Act, in exercise of power whereunder the Notifications had been issued does not require the consultations with the Drugs Technology Advisory Board (DTAB) constituted under Section 5 of the Drugs Act or with the DCC.

8. The petitioner has filed a rejoinder, pleading:

(i) that from the counter affidavit of the respondents, it stands admitted:

(a) that the respondents had knowledge that the petitioner had been granted licence to manufacture and market Corex as far back as on 10th March, 1995 but inspite thereof, the respondents did not issue any notice to show cause or grant an opportunity of hearing to the petitioner;

(b) that the list of new drugs including FDCs published on the website of CDSCO in the year 2013 had admittedly failed to include Corex therein and which list was subsequently rectified;

(ii) that as evident from the terms of reference thereof, the Kokate Committee was constituted for the limited purpose of examining the FDCs permitted for manufacture and sale in India by various SLAs without prior approval of Drugs Controller; the scope of reference of Kokate Committee was targeted at manufacturers and distributors who were undertaking activities merely on the basis of SLA approvals, without prior approval from Central Government; however the petitioner has a licence from the Drugs Controller to manufacture Corex;

(iii) that the findings of the Kokate Committee thus have no relevance to Corex;

(iv) that the report of Kokate Committee also does not refer to or provide any cogent evidence or scientific data whilst arriving at its recommendation to prohibit manufacture, distribution and sale of Corex;

(v) that though the impugned Notification prohibited the manufacture of the combination of Corex on the ground of therapeutic justification but the recommendations of Kokate Committee purport to state that the combination of Corex does not have therapeutic value;

(vi) that under Section 26A of the Drugs Act therapeutic justification is clearly in relation to ingredients and / or the quantity of ingredients;

(vii) that the report of Kokate Committee fails to consider the ingredients and / or the quantity of ingredients of Corex;

(viii) that the impugned Notification is inconsistent with the report of Kokate Committee;

(ix) that the Kokate Committee as per its report analysed 1083 FDCs within a period of six days from 4th January, 2016 to 9th January, 2016 and suffers from non-application of mind and perversity;

(x) that the report of Kokate Committee though records that those combinations that had already been approved by the Drugs Controller had been inadvertently included in the list of drugs categorised as 'irrational' and in which Corex is included but still proceeds to recommend ban on Corex;

(xi) that merely because Corex was not mentioned in the list published on the website of CDSCO in 2013 does not alter the fact that the petitioner had obtained the necessary licence for manufacture and sale of Corex from the Drugs Controller as far back as in March, 1995;

(xii) that the petitioner was thus entitled to receive a specific show cause notice and opportunity to be heard before the impugned Notification;

(xiii) that since the petitioner was holding a licence from the Drugs Controller, there was no need for them to make a fresh application or to make any representation;

(xiv) that the reliance on the Minutes of the 48th Meeting of DCC is misplaced as the issues discussed therein do not pertain to rationality, efficacy and safety of Corex; rather the issues discussed at the said meeting pertain to rampant misuse and illegal export of Corex;

(xv) Section 26A does not contemplate misuse and abuse as a ground for prohibition.

9. The hearing on the first three days i.e. 28th, 29th and 30th March, 2016 revolved around, whether the FDCs subject matter of impugned Notifications are a 'new drug' within the meaning of Rule 122A, what was the status of FDCs which, even though qualified as a 'new drug' but licence for manufacture whereof had been granted prior to the incorporation of 'new drug' in the Drugs Rules, whether they required approval from the Drugs Controller, etc. It was *inter alia* the contention of the learned ASG that of the 344 FDCs which have been banned/prohibited by the impugned Notifications, only 4 or 5 had the approval of the Drugs Controller. It was further stated that only 5 or 6 FDCs find mention in the Indian Pharmacopeia and they are not included in the FDCs which have been banned. Per contra it

was the contention of the senior counsels for the petitioners that the FDCs did not require the approval of the Drugs Controller, being not a 'new drug' and manufacturing thereof having been permitted by the Authorities under the Drugs Act.

10. Finding that the Impugned Notifications were not on the ground of the petitioners or any of them not having the requisite approval, it was enquired from the learned ASG, why the said aspect should be gone into in these petitions when that is not the ground on which the Notifications impugned in the petitions had been issued.

11. The learned ASG agreed that the hearing can go on without going into the aspect of approvals and leaving it open to the respondents to, if so desire, take up the said aspect separately. Accordingly, in the order dated 30th March, 2016, it was clarified that "this Court in adjudicating these petitions or even for the purpose of the interim relief therein is not entering into the question whether the petitioners have the requisite approval for manufacture of the FDC drugs qua which Notifications dated 10th March, 2016 have been issued and will be deciding the validity of the Notifications *de hors* the said aspect". Earlier, on 28th March, 2016, it had already been clarified that this Court in these petitions is concerned only with the ban under the impugned

Notifications and the interim orders in the petitions will not come in the way of the respondents taking action under any other provision.

12. Though during the subsequent hearings, inspite of it being so clarified, the said aspect of approvals kept surfacing but in view of the clarification issued on 30th March, 2016 I am in this judgment not adjudicating the said aspect.

13. For *inter alia* the aforesaid reason, I am in this judgment also not following my usual style of judgment writing, of recording the submissions of counsels in detail as the same would unnecessarily burden the judgment, when all submissions made are not for adjudication.

14. After hearing the senior counsels for the petitioners till 30th March, 2016, in the order dated 30th March, 2016, it was also recorded as under:

> *"5. The senior counsel for the petitioner in W.P.(C) No.2212/2016 has also drawn attention to the letter dated 1st October, 2012 of the Ministry of Health and Family Welfare, Government of India to Health Secretaries of all States/Union Territories directing them not to grant licence for manufacture, for sale or for distribution of FDC drugs and to order dated 16th September, 2014 of the Government of India, Ministry of Health and Family Welfare constituting the Committee under the Chairmanship of Professor Chandrakant Kokate on whose recommendation the impugned Notifications have been issued.*
> *6. A perusal of the order dated 16th September, 2014 shows that the reason and purpose of constitution of the said Committee was:-*

(a) that the States/Union Territories though not entitled to grant manufacturing licences for drugs falling under the definition of 'New Drugs' had granted such licences inspite of directives not to grant such licences and the last of which directives was contained in the letter dated 1st October,2012 supra.

(b) in respect of licences granted to manufacture FDC drugs falling under the definition of 'New Drugs' licensed by State Licensing Authorities before 1st October, 2012 without permission of DCGI, it was decided that DCGI would ask all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within a period of 18 months failing which such FDCs will be considered for being prohibited for manufacture.

(c) in response thereto applications with respect to many such FDCs for examination were received.

(d) the Committee was being constituted to examine such a huge number of applications in a timely manner.

(e) the terms of reference to the Expert Committee were also to advise DCGI and examine the rationality as well as safety and efficacy of FDCs which fall under the definition of 'New Drugs' and are licenced by State Licensing Authorities without due approval of DCGI.

7. It would thus appear that the Committee of Professor Kokate on whose recommendation the impugned Notifications have been issued was constituted not to consider exercise of power under Section 26A of the Drugs and Cosmetics Act, 1940 but to consider whether the licences / approvals sought by existing manufactures of FDCs with licences from State Authorities, in pursuance to the directive of the Government of India to also seek the approval of the DCGI, were to be granted.

8. The senior counsel for the petitioner in W.P.(C) No.2212/2016 in response to a query informs that such permission was sought under Rule 122B of the Drugs and Cosmetics Rules, 1945, as for a new drug. He also contends that at least the petitioner in W.P.(C) No. 2212/2016 has the approval of DCGI also.

9. I have wondered whether power under Section 26A can be exercised by the Central Government in pursuance to recommendations of a Committee constituted to consider

applications for approval of a new drug under Rule 122B of the Drugs and Cosmetics Rules, 1945. Prima facie it appears that consideration of application under Rule 122B can either result in grant of approval or rejection of approval. I am informed that rejection of approval is appealable under Rule 122DC.

10. The power under Rule 122B of approval or disapproval of new drug has to be exercised by the Licensing Authority i.e. DCGI. A question also arises whether DCGI can delegate such power to an external Committee and whether such committee followed the procedure prescribed to be followed under Rule 122B and if not to what effect.

11. It is also the contention of senior counsel for the petitioner in WP(C) No. 2212/2016 that the statutory technical bodies, also constituted under the Act to perform technical functions under the Act have not been involved in the decision making process leading to impugned notifications.

12. It is yet further the contention that though the FDCs have been in the market for years, if not decades but it was not considered that there are no complaints with respect thereto.

13. In view of the aforesaid, it is deemed appropriate to, before hearing the other appearing counsels/senior counsels, the learned ASG be heard particularly on the aforesaid aspect. I have recorded my thought process so that the doubts arising in my mind can be addressed by the learned ASG. A draft of this order be circulated.

14. List for arguments of the learned ASG on 31st March, 2016."

15. The learned ASG, on the next dated i.e. 31st March, 2016 clarified (and as recorded in the order of that date):-

"9. Learned ASG before commencing his arguments, with reference to the draft order has clarified i) that his stand was / is that the petitions be decided on the basic issue pertaining to decision making process under Section 26A of the Drugs and Cosmetics Act; nonetheless the question whether the petitioners have the requisite approvals / licence will have to be gone into to determine the locus standi of the petitioners to maintain the petitions inasmuch as no relief can be granted to the petitioners who do not even have the requisite approvals for manufacture of the concerned FDC; ii) that para 6 of yesterday's order mixes up between the recitals of the order dated 16th September, 2014 and

the terms of reference to the Kokate Committee; iii) that the terms of reference were wide enough to cover Section 26A; and, iv) that applications received and which were referred to Kokate Committee were not under Rule 122B."

16. I am of the view that, merely for the purpose of determining the *locus standi* of each petitioner to maintain the respective petition no conclusive finding in this judgment with respect to the licence if any held by the petitioner in each of the petitions for manufacturing the FDC with respect to ban whereof vide Notification under Section 26A the petition is filed, need to be given. Suffice it is to state that with respect to whichever petition the counsel for the respondents stated that copy of licence had not been filed with the petition, the counsel therein made up the deficiency.

17. In response to the query raised on 30th March, 2016 and as recorded in para 9 of the order of that date and reproduced above, Dr. Sumani, Joint Drugs Controller General of India, on 18th April, 2016 informed (and as recorded in the order of that date) that in the issuance of impugned Section 26A Notifications, Drugs Controller was not involved. Vide order dated 12th May, 2016, the learned ASG was granted opportunity to place on record the Standard Operation Procedure (SOP) to be followed by Drug Controller in considering an application under Order 122B. The same was handed over.

18. I may in this context also note that having gone through the Drugs Acts and though finding the preamble thereof providing that the enactment thereof is to regulate *inter alia* the manufacture of drugs but not finding any provision therein to regulate the manufacture of drugs, I, during the hearing on 4th April, 2016 wondered, in the context of which provisions pleas in the counter affidavit of the respondents, of the licences having been issued by the SLAs without the Drugs Controller approving the drugs, were taken.

19 The learned ASG on 6th April, 2016 very frankly admitted that the Drugs Act when enacted in the year 1940 was concerned primarily with import of drugs as there were then no manufacturing facilities in India and thus this lacuna has remained in the same inspite of amendment from time to time. He in this context also drew attention to the Drugs and Cosmetics (Amendment) Act, 1982, as per the 'Statement of objects and reasons' whereof though the need for amendment arose to impose more stringent penalties on anti social elements indulging in manufacture or sale of adulterated, spurious drugs not of standard quality which were likely to cause death or grievous hurt to the user, but the opportunity was being availed of to also incorporate provisions on the other aspect of effective control on the manufacture of drugs to empower the Central Government to

prohibit import or manufacture of drug in public interest, where the Government is satisfied that use of any drug is likely to involve risk to human beings.

20. I, on 6th April, 2016, suggested to the learned ASG that now that he himself was stating that the Drugs Act was primarily dealing with the import of drugs and was not found to have any substantive provision regarding 'controlling and regulating the manufacture of drugs', to make necessary recommendations to the Government either for re-enactment or for amendment thereof. I am happy to note that in the last about one month there has been news report of a relook being had by the authorities concerned qua the Drugs Act and the proposal to enact a new law.

21. The senior counsels/counsels for the petitioners made extensive arguments on the merits of the reasons given by the Kokate Committee for banning each of the 344 FDCs and which were rebutted by the learned ASG. However, the need to record the said contentions or to adjudicate the same is also not felt as I am of the view that the same is beyond the scope of judicial review.

22. Supreme Court in ***Vincent Panikurlangara Vs Union Of India*** (1987) 2 SCC 165 was concerned with a petition seeking ban on import,

manufacture, sale and distribution of such drugs which had been recommended for banning by the DCC. A prayer in the petition was also made for cancellation of all licences authorising import, manufacture, sale and distribution of such drugs. Interestingly, the claim in that petition also was for withdrawal of 7000 FDCs. It was held that the issues that fell for consideration were not only relating to technical and specialised matters relating to therapeutic value, justification and harmful side effect of drugs but also involved examination of correctness of action taken by the Union of India and the Drugs Controller on the basis of advice ; the matter also involved the interest of manufacturers and traders of drugs as also the interest of patients who require drugs for their treatment. It was further held that "having regard to the magnitude, complexity and technical nature of the enquiry involved in the matter and keeping in view the far reaching implications of the total ban of certain medicines.....a judicial proceeding of the nature initiated is not an appropriate one for determination of such matters". It was yet further held that "the technical aspects which arise for consideration in a matter of this type cannot be effectively handled by a court" and that "no final say in regard to such aspects come under the

purview of the court". Accordingly, the petition was disposed of by issuing certain directions to the Central Government.

23. Though the judgment aforesaid is more than 25 years old but what was observed therein holds good today also. It is not as if in the last more than 25 years since the said judgment the Courts have acquired any skill or developed any mechanism for deciding the questions which the Supreme Court then held were outside the judicial purview. The same view has been reiterated in some of the subsequent judgments also mentioned hereunder, in other context. Thus, I hold that the challenge by the petitioners to the impugned Notifications on merits thereof does not lie before this Court by way of a petition under Article 226 of the Constitution of India.

24. Even otherwise, the well settled principles of exercise of power of judicial review also do not permit this Court to, in exercise of powers under Article 226 of the Constitution of India, enter into the merits of the decision taken by the Government. Judicial review has to be of the decision making process and not of the decision, except within the well defined parameters. Though the senior counsels for the petitioners particularly the petitioner in W.P.(C) No.2212/2016 had also contended that the decision on merits also is capable of being set aside in exercise of powers under Article 226 within the

said parameters but the need for that also is not felt for the reasons hereafter appearing.

25. That takes me back to the queries raised and as recorded in the order dated 30th March, 2016 the relevant part whereof has been re-produced in para 14 hereinabove. I now proceed to consider, whether it was incumbent upon the Government of India to, in exercise of power under Section 26A of the Drugs Act involve the bodies constituted under the said Act.

26. Section 5 of the Drugs Act mandates the Central Government to constitute a Board [to be called the Drugs Technical Advisory Board (DTAB)] "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". DTAB has been statutorily prescribed to comprise of (i) the Director General of Health Services; (ii) the Drugs Controller; (iii) the Director of the Central Drugs Laboratory, Calcutta; (iv) the Director of the Central Research Institute, Kasauli; (v) the Director of Indian Veterinary Research Institute, Izatnagar; (vi) the President of Medical Council of India; (vii) the President of the Pharmacy Council of India; (viii) the Director of Central Drug Research Institute, Lucknow; (ix) two persons to be nominated by the Central Government from among

persons who are in charge of drugs control in the States; (x) one person to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto; (xi) one person to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto; (xii) one person to be nominated by the Central Government from the pharmaceutical industry; (xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research; (xiv) one person to be elected by the Central Council of the Indian Medical Association; (xv) one person to be elected by the Council of the Indian Pharmaceutical Association; and, (xvi) two persons holding the appointment of Government Analyst under the Act and to be nominated by the Central Government. The term of office of the nominated and elected members of DTAB has also been prescribed as three years or for so long as they hold the appointment of the office by virtue of which they are nominated or elected. DTAB, vide Section 5(4) has been authorised to frame its bye-laws fixing a quorum and regulating its own procedure and the conduct of all business and vide sub section (5) to constitute sub-committees

for consideration of particular matters. The Central Government has been mandated vide sub section (7) to appoint a person to be the Secretary of DTAB and to provide DTAB with clerical and other staff necessary.

27. Section 6 of the Drugs Act mandates the Central Government to 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 the Act or by any Rules made thereunder. Section 6 empowers the Central Government to "after consultation with" DTAB make Rules prescribing the functions of the Central Drugs Laboratory and the procedure for analysis or tests of the drugs and for such other matters as may be necessary.

28. Section 7 mandates the Central Government to constitute an Advisory Committee to be called the Drugs Consultative Committee (DCC) "to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act". The DCC has been prescribed to consist of two representatives nominated by the Central Government and one representative nominated by each of the State Governments.

29. Section 16 requires a drug to comply with the standards set-out in the Second Schedule to the Act and empowers the Central Government to "after consultation with" DTAB and after giving notice by notification in the Official Gazette of not less than three months of its intention, amend the said Second Schedule.

30. Section 18 prohibits, after such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, manufacture or sale of drugs which are not of standard quality except under and in accordance with the conditions of a license issued for such purpose. The second proviso thereto however enables the Central Government to, after consultation with the DTAB, by notification in the Official Gazette, permit the manufacture or sale of any drug not being of standard quality. Vide Section 16(1) "standard quality" means the standards set out in the Second Schedule.

31. Section 26A of the Drugs Act, in exercise of powers whereunder the Central Government has issued the impugned Notifications, is as under:-

> "**26A. Power 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."

32. The question which arises is, is the Central Government entitled to exercise the power under Section 26A without consulting or even involving the DTAB and the DCC. Further question which arises is, whether the Central Government can exercise the said power in consultation with and on the advice and recommendation of, another Committee, though also of technical persons only, constituted by the Central Government.

33. The contention of the senior counsels for the petitioners of course is that the Central Government cannot so act on technical matters, instead of on the advice of and in consultation with the statutory bodies aforesaid, in consultation with and on advice and recommendation of a non-statutory Committee. It was contended that as per the Report filed by the respondents in Civil Writ Petition No.698/1993 titled ***Drug Action Forum Vs. Union of India*** in the Supreme Court, the technical sub-Committee of DTAB had found the guidelines on ingredients of cough mixtures to be in order and

which guidelines *inter alia* provided that FDCs for dry cough to contain a centrally acting antitussive, either alone or with one or more drugs which complement its action peripherally by different mechanism along the path of the cough reflex e.g. (i) antihistanines, (ii) decongestants and (iii) expectorants. Attention was also invited to the letter dated 10th March, 1995 of the Drugs Controller to the petitioner in W.P.(C) No.2212/2016 conveying no objection to the marketing of Corex cough syrup with the same formulation as has been banned today. It was contended that the very fact that the Drugs Controller had granted approval, implied that there was therapeutic justification for both ingredients and now the non-statutory Committee has disagreed therewith, that too without carrying out any tests.

34. Per contra, the learned ASG argued (i) that Section 26A is without prejudice to any other provision of Chapter IV in which Section 26A is located and the power thereunder is to be exercised by the Central Government on its own satisfaction; (ii) that DTAB is not involved in the grant of approval to any drug and thus cannot have any compulsory role in prohibition of any drug; (iii) that even DTAB under Section 5(5) is entitled to include outsiders; (iv) the exercise of powers under Section 26A is only partially technical but is essentially legislative; (v) there is no mandate to the

Central Government in the Drugs Act or the Drugs Rules to, before the exercise of powers under Section 26A, take advice from DTAB; (vi) the statute lists the role of DTAB in Sections 6(2), 7(1), 8(2) second proviso to Section 10, 12(1), 16(2), second proviso to Section 18 and Section 33; on the contrary there is no such requirement in Section 26A.

35. The learned ASG, on enquiry, as to on what basis he called the exercise of power under Section 26A to be legislative in nature, stated that any act of general application is a legislative act and once the act qualifies as a legislative act, there is no need to provide an opportunity of hearing to those affected or likely to be affected thereby. It was further contended that the scope of judicial review qua a legislative act would also be different; the Court would then not interfere with the satisfaction reached by the authority vested with the exercise of power. Reliance was placed on:-

(i) ***Union of India Vs. Cynamide India Pvt. Ltd.*** (1987) 2 SCC 720 where the Drugs (Price Control) Order, 1979 of the Central Government in exercise of powers under Section 3(2)(c) of the Essential Commodities Act, 1955 was held to be a legislative action and it was further held that legislative action, plenary or subordinate is not subject to rules of natural justice;

(ii) ***Sitaram Sugar Company Ltd. Vs. Union of India*** (1990) 3 SCC 223 also laying down that a statutory instrument such as a rule, order or regulation emanates from the exercise of delegated legislative power which is part of the administrative process resembling enactment of law by the legislature and a party affected by the order has no right to notice and hearing, unless the statute so requires;

(iii) ***Prag Ice and Oil Mills Vs. Union of India*** (1978) 3 SCC 459 similarly holding with respect to Mustard Oil (Price Control) Order 1977 and observing that the Parliament having entrusted the fixation of prices to the expert judgment of the Government, it would be wrong for the Court to examine each and every minute detail pertaining to the governmental decision and that the Government is entitled to make pragmatic adjustments;

(iv) ***State of Punjab Vs. Tehal Singh*** (2002) 2 SCC 7, in the context of issuance of Notifications establishing Gram Sabha areas and constitution of Gram Sabhas in exercise of powers under the Punjab Panchayati Raj Act, 1994 holding, that a legislative act is the creation and promulgation of a general rule of conduct without reference to a particular case and is distinct from an administrative act of making and issuance of a specific direction or the application of a general rule to a particular case in accordance with the requirements of policy and

further holding that where provisions of a statute provide for the legislative activity i.e. making of a legislative instrument or promulgation of general rule of conduct or a declaration by a notification by the Government that a certain place or area shall be part of a Gram Sabha and does not concern the interest of an individual but relates to public in general, it will qualify as a legislative act.

36. It was further contended that the power of the Central Government under Section 26A of the Drugs Act entitles the Central Government to even undo what the Drugs Controller had done and that DTAB is not expert body and cannot exercise its power as was required. It was yet further contended that no *mala fides* have been attributed to the Kokate Committee or to the decision making process of the Central Government or even for non-involvement of DTAB.

37. In response to the contention that Kokate Committee was not constituted to advise on exercise of powers under Section 26A but to examine the applications for approval of FDCs for which SLAs had granted licences between September, 1988 and 1st October, 2012, reliance was placed by the learned ASG on ***State of U.P. Vs. Hindustan Aluminium Corporation*** (1979) 3 SCC 229 to contend that the Government could

always alter the scope of exercise already begun and it was contended that all technical requirements have been satisfied.

38. The senior counsels for the petitioners referred to ***Ramlila Maidan Incident Vs. Home Secretary, UOI*** (2012) 5 SCC 1 to contend that when the statute provides for establishment of expert body, creation of an *ad hoc* body and reliance on the information thereof was wrong.

39. I am unable to agree with the contention of the learned ASG that exercise of power under Section 26A is only partially technical, whether it be legislative or not. Section 26A does not vest the Central Government with a carte blanche to regulate, restrict or prohibit the manufacture, sale or distribution of a drug. The Central Government can exercise power thereunder only when satisfied that the drug involves risk to the consumers thereof or does not have any therapeutic value or contains ingredients of which there is no therapeutic justification 'and' that in public interest it is necessary or expedient to regulate, restrict or prohibit that drug. Thus, power of regulation, restriction or prohibition under Section 26A cannot be exercised in public interest, for any reason other than the drug posing a risk to consumers thereof or having no therapeutic value or no therapeutic justification. This is evident from the use of the word "and" instead of "or".

There is no reason to, in Section 26A, read "and" as "or". The decision on the question, whether a drug is risky or does not have therapeutic value or does not have therapeutic justification cannot be a matter of policy but has to be based on scientific technical reasons. It is for this reason only that the Supreme Court in ***Vincent Panikurlangara*** supra refused to be drawn into examining whether the drugs qua which directions were sought were indeed risky for consumers or had no therapeutic justification or had no therapeutic value.

40. Though Section 26A starts with the words "Without prejudice to any other provision contained in this Chapter" but Sections 5, 6 & 7 aforesaid providing for constitution of DTAB, Central Drugs Laboratory and DCC "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" and " to carry out the functions entrusted to it by this Act or any Rules made thereunder" or "to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India of this Act" are not to be found in Chapter-IV in which Section 26A has been placed and are placed in Chapter-II and thus the provisions of Section 26A do not override the provisions of

Sections 5 to 7 and/or are not without prejudice thereto, as was suggested by the learned ASG. Moreover, the words 'without prejudice to any other provision' do not negate the other provisions but rather signify that provision which is preceded by these words is in addition to the other provisions. As far back as in ***King-Emperor Vs. Sibnath Banerji*** AIR 1945 PC 156 and approved in ***Shiv Kirpal Singh Vs. V.V. Giri*** (1970) 2 SCC 567 it was held that when this expression is used, anything contained in the provision following this expression is not intended to cut down the generality of the meaning of the preceding provision. Supreme Court, in ***Commissioner of Income Tax Vs. Eli Lilly Company (India) Private Ltd.*** (2009) 15 SCC 1, in the context of Section 201(1) and Section 201(1A) of the Income Tax Act, 1961 also held that such words mean that the provisions of both the sub-sections are to be considered independently without affecting the rights mentioned in either of the sub-sections.

41. Chapter-IV of the Drugs Act in which Section 26A is placed contains Section 16 regarding standards of quality and power of the Central Government as aforesaid to amend the same with three months notice, Sections 17, 17A, 17B regarding Misbranded Drugs, Adulterated Drugs and Spurious Drugs respectively, Section 18 containing prohibition of

manufacture and sale of certain Drugs by the State Governments and the Central Government and Sections 18 to 26 providing for machinery for enforcement of standards of quality. Section 26B to Section 33A, also in Chapter-IV provide for regulation by Central Government of manufacture of Drugs in public interest and penalties for contravention. Thus, when Section 26A uses the words "Without prejudice to any other provision contained in this Chapter", all that the same means is that conferment of power on Central Government under Section 26A does not have the effect of depriving the Central Government from expressing other powers under other Schemes in the same Chapter of the Act. A drug can thus cease to be of standard quality resulting in the manufacture thereof being prohibited, if the standard prescribed is amended by the Central Government. However the same does not prevent the Central Government from prohibiting manufacture thereof under Section 26A if provisions thereof are also satisfied. All that the words "Without prejudice to any other provision in the Chapter" mean is that powers under each Section of Chapter-IV is independent of each other. Thus no benefit can be drawn by the respondents from the use of the said words.

42. Though undoubtedly Section 26A does not require the satisfaction thereunder of the Central Government to be in consultation with or on the

aid, advice or recommendation of DTAB and/or DCC or after having the requisite tests carried out from the Central Drugs Laboratory but a mere absence of the said words from Section 26A would not mean that Section 26A is to be read in isolation. Realising that the functions to be performed by the Central and the State Governments under the Drugs Act are not administrative, but largely technical, the Drugs Act has devised the machinery for advising the Central and the State Governments on such technical matters arising out of the administration of the Act and to carry out the functions assigned to them under the Act. Merely because the powers vested in the Central Government vide some other Sections of the Act expressly provide for exercise thereof on advice of or in consultation with DTAB and/or DCC does not take away from the wide language used in Sections 5&7 while prescribing the purpose of constitution of DTAB & DCC, to advise the Central Government on technical matters arising out of administration of the Act and to carry out other functions assigned to Central Government by the Act. The said words are of general application and it will be in the domain of DTAB to advise the Central Government in exercise of all technical powers under the Act, whether the relevant Section prescribes for the Central Government to before exercising of power thereunder take

advice of Central Government or not. The need, notwithstanding the generality of the language of Sections 5&7, to expressly provide for advice/consultation appears to have been felt to remove any doubt whether in discharge of power thereunder DTAB/DCC were to be consulted or not. A statute establishing a body/institution to advise the Central Government in exercise of powers thereunder *ipso facto* places a reciprocal obligation on the Central Government to take the advice of such body/institution. Supreme Court, as far back as in ***K.N. Guruswamy Vs. State of Mysore*** AIR 1954 SC 592 held that once the legislature has deemed it wise not to leave the matter to the unfettered executive discretion and has enacted law from which a policy and purpose is evident, the fetters imposed by legislation cannot be brushed aside at the pleasure of the Government or its officials – The Rules bind the State and the subject alike. Reference in this regard can also be made to ***Ram Singh Vs. Union of India*** (2015) 4 SCC 697 holding that though undoubtedly Article 16(4) confers power on the Central Government to bypass the National Commission for Backward Classes and to include groups of citizens in the Central List of Other Backward Classes (OBCs) on the basis of Article 16(4) itself but enactment of the specific statutory provision constituting a Commission cannot be overlooked. It was further

held that Central Government cannot be permitted to discard the statutory norms.

43. Great care has been taken in the Drugs Act to describe the constitution of DTAB and the DCC. The Drugs Act is a pre-Constitution law made by the Central Legislature under the Government of India Act, 1935. The subject matter of the Act, on coming into force of the Constitution of India falls under Entry 19 List 3 of the Seventh Schedule to the Constitution of India. Under the said Act the regulation of manufacture, sale and distribution of drugs is primarily the concern of the State Authorities while the Central Authorities are responsible for approval of new drugs, clinical trials in the country, laying down the standards of drugs. It is for this reason that in DTAB as well as DCC representation of the State Governments has been provided. Both DTAB and DCC are broad based bodies having representation also from other statutory institutions and institutions set-up by the Government and having the knowledge and role to play in the functions for discharging which DTAB and DCC have been constituted. Though the Drugs Act does not lay down the procedure for appointment of the Director of the Central Drugs Laboratory but the very fact that the same has been provided to be established to carry out functions entrusted to it by the Act or

the Rules thereunder and by its very name suggests i.e. to carry out the analysis tests and submit reports on the drugs, it is evident that as to what will be the criteria for such appointment.

44. The provision in the Drugs Act for constitution of DTAB and DCC as also in several other statutes for establishment of bodies/institutions for discharge of powers thereunder, is not without purpose. The reason is to ensure institutional integrity and compliance of public law principles in discharge of functions and exercise of power thereunder. Though the legislature, in the Drugs Act, vested the Central Government with the powers to be exercised thereunder but at the same time constituted DTAB to advice the Central Government on technical matters arising out of administration of the Drugs Act and to carry out other functions assigned to the Central Government by the Act and the DCC, also to advice the Central Government and the DTAB on any matter tending to secure uniformity throughout India in administration of the Act. The role of DTAB thus is not qua technical matters only but extends to advising the Central Government in carrying out other functions assigned to it by the Act also. Without such institutions, the Central Government in the discharge of various functions including of a technical nature which it is required to discharge under various statutes or its

Governmental functions would be left with a discretion to choose and appoint whosoever it may at that point of time desire for advising it on the matter and which may render the decision of the Central Government open to challenge on the grounds of bias and competence in the matter of selection.

45. Even otherwise it defies logic as to why would the Central Government, when has available to it the machinery provided under the Drugs Act itself to discharge the functions of a technical nature under Section 26A, would, instead of using the said machinery choose to follow another course of action. The only reason which I have been able to gather is that the constitution of the Kokate Committee does not owe its genesis to advise the Government in the matter of discharge of functions under Section 26A but for the purposes of scrutinising the applications called for and received.

46. The respondents, in their counter affidavit have not disclosed any reason for the Central Government, before issuance of the Notifications impugned in these petitions, not taking the advice of and consulting DTAB or DCC or to not have the FDCs which were proposed to be prohibited under Section 26A tested, examined and analysed by the Central Drugs Laboratory.

47. Supreme Court in ***Vincent Panikurlangara*** supra as aforesaid was also concerned with a demand in public interest for banning 7000 FDCs on the ground of the same being injurious to public health. Supreme Court as aforesaid held that it was beyond judicial review to determine whether the FDCs of which ban was sought were indeed injurious to public health. However the Supreme Court found (i) that the Hathi Committee, appointed by the Central Government in its Report submitted in 1974, highlighted the havoc played by multinational corporations in Indian scene and pleaded for nationalising the drug industry in the best interest of the Indian people; (ii) the said recommendation was not accepted by the Government; (iii) that in 1980, the DCC set up a sub-Committee of experts for screening formulations of drugs prevalent in the Indian market from the point of therapeutic rationale in order that irrational and harmful combinations of drugs could be banned; (iv) the said Sub Committee of experts recommended banning of twenty FDCs; (v) The sub- Committee's Report was approved by the DCC as well as the Ministry of Heath in 1981; (vi) the Central Drugs Controller issued directions to the State Authorities to strictly enforce the ban on drugs pertaining to these combinations; (vii) however on account of slackness in the enforcement machinery these drugs were still prevalent in the market;

(viii) that though the Drugs Act was amended w.e.f. 1st February, 1983 *inter alia* to insert Section 26A but owing to interim orders given by the Courts, in petitions challenging *vires* thereof, the benefit of the new power conferred on the Central Government was till then not available; (ix) that the Report of the sub-Committee aforesaid besides being considered by the DCC was also considered by the DTAB; (x) though the Court had issued notice to the Medical Council of India and the Indian Medical Association but both had failed to respond; (xi) not only a judicial proceeding of the nature initiated was not an appropriate one for determination of such matters but perhaps the Hathi Committee too was not one which could be considered as an authoritative body competent to reach definite conclusions; (xii) no adverse opinion could therefore be framed against the Central Government for not acting upon its recommendations; (xiii) the question involved in the matter was a question of policy; (xiv) no final say in regard to such aspects comes under the purview of the Court; (xv) what is considered to be the best medicine today for treatment of a particular disease becomes out of date and soon goes out of the market with the discovery or invention of new drugs; (xvi) the problem was likely to arise from time to time; (xvii) the Central Government on the basis of expert advice can indeed adopt and approve

national policy; (xviii) it is State's obligation to enforce production of qualitative drugs and elimination of the injurious ones from the market; (xix) the process of regulation has to be strengthened; (xx) there is an immediate need for central enforcement machinery in the interest of community at large; (xxi) licencing of manufacture should also be centralised so that uniformity can be maintained; (xxii) Section 5 of the Drugs Act authorises constitution of a Central Drugs Technical Advisory Board as also a State Board for each State; (xxiii) the object of setting up of such Boards is to advise the respective Governments on technical matters arising out of the administration of the Act; sub-Section (2) provides for the manning of the Central Board; (xxiv) adequate representation should be provided to consumers and at least two capable representatives from out of their category should be nominated by the Central Government; (xxv) the manning of DTAB should be such as in its functioning it would be in a position to effectively advise the Central Government on all technical matters; (xxvi) Section 7 provides for setting up of DCC and its statutory purpose is to advise the Central Government, the State Governments and the DTAB on any matter tending to secure uniformity throughout India in the administration of the Act; (xxvii) in DCC also there should be adequate

representation on behalf of the consuming public; (xxviii) the Central Government should set-up regional Drug Laboratories in addition to the Central Laboratory as provided by Section 6 of the Act; (xxix) though DCC was existing but Central Government should consider whether it requires to be broad-based and confined with larger scope of operation the Supreme Court was not examining the objections raised with reference to specific medicines as writ was not an appropriate proceeding therefor; and, (xxx) however the Central Government should take into consideration the objections and have the same referred to the DCC. Though the Supreme Court as far back as in ***Vincent Panikurlangara*** also held that the matters such as these should be examined by the DTAB, DCC and Central Drugs Laboratory constituted under the Drugs Act and that the Report of the Hathi Committee then constituted was not authoritative but the Government of India has issued the impugned Notifications dated 10th March, 2016 on the recommendations of the Kokate Committee (which is on the same footing as Hathi Committee) and without consulting either DTAB, DCC or Central Drugs Laboratory.

48. It was not the contention then of the respondents that DTAB and DCC were incapable of rendering such services. If it is the case of the respondents

today that DTAB and DCC as constituted are incapable of rendering the services as Kokate Committee has rendered to the respondent no.1, then that shows a serious flaw in the constitution of DTAB and DCC. The contention thus of the learned ASG that DTAB and DCC were incapable of rendering such services cannot be accepted.

49. I was in ***Buddhadev Maity Vs. Union of India*** MANU/DE/1035/2010 and against which no appeal is found to have been preferred concerned with the challenge to the order of the Central Government in exercise of power under Section 10 of the Contract Labour (Regulation and Abolition) Act, 1970 deciding not to prohibit employment of contract labour in normal maintenance, repair or emergency shut down and operation works in Mechanical Division of Haldia Refinery. Section 3 of the said Act provides for constitution of a Central Advisory Contract Labour Board to advise the Central Government on such matters arising out of administration of that Act as may be referred to it to carry out other functions assigned to it under the Act. Similarly Section 4 of the Act provides for constitution of State Advisory Boards and Section 5 for constitution of Committees by the Central Board and the State Boards. Though Section 10 of the said Act expressly required the Central Government or State

Governments to after consultation with the Central Board or the State Boards prohibit employment of contract labour in any process, operation or other work in any establishment but finding that the impugned order had been issued without the Board though approached rendering any advice the petition was allowed. Reliance was placed on (A) ***Gujarat Working Class Union Vs. State of Gujarat*** MANU/GJ/0241/1994 (DB) laying down that the object of consultation with the Board is not merely to collect information which the Government could have collected through its own departments or other agencies; it was held that "consult" implies a conference of two or more persons or impact of two or more minds to enable them to evolve a correct solution; it was further held that without any meaningful dialogue with the Board and interaction of views and thoughts, there was no consultation of the Government with the Board, which is mandatory; direction to re-examine the matter in accordance with law was issued; (B) ***Indian Airports Employees Union Vs. Air India*** MANU/MH/0260/1996 (DB) holding that Section 10 (1) imposes a duty on the appropriate Government to consult the Board and that the advice of the Board has to be discarded for sound reasons; it was held that the Boards consist of representative of the workmen, of the industry and appropriate Government

and so the consultation with these Boards means that the representatives of the contractor, the workmen and industry will have a voice in expressing their views when the Board is being consulted with regard to the proposal whether the contract labour should be prohibited or not; it was further held that the Act does not vest absolute discretion in the appropriate Government to prohibit contract labour; matter was remanded for fresh decision; (C) ***M/s L & T Mc. Neil Ltd. Vs. Government of Tamil Nadu*** (2001) 3 SCC 170 laying down that the views of the Board are to be ascertained for the purpose of assisting the Government in reaching its conclusion on the matter one way or the other and the Government could not have reached the conclusion one way or the other in the absence of any advice of the Board; the decision of the Government in issuing the notification under Section 10(1) was thus held to be vitiated; and, (D) ***M/s. Zenith Industrial Services Vs. Union of India*** 1990 I LLJ 38 (Orr) (DB) also holding that the power under Section 10 has to be exercised in the manner indicated therein and prior consultation with the Advisory Board is a must to prevent the Government from misusing or abusing the power or exercising it arbitrarily. Reference was also made to ***Ex-Capt. Harish Uppal Vs. Union of India*** (2003) 2 SCC 45 holding that no Body or Authority, statutory or not, vested with powers can abstain from

exercising the powers when an occasion warranting such exercise arises and that power vested in a public authority is coupled with a duty to exercise it when a situation calls for such exercise and the Authority cannot refuse to act at its will or pleasure and the Courts will always have the authority to compel or enforce the exercise of the power by the Statutory Authority and will issue directions as are necessary to compel the Authority to do what they should have done on their own. Reference was also made to ***Chandramouleshwar Prasad Vs. The Patna High Court*** (1969) 3 SCC 56 holding that consultation or deliberation is not complete or effective before the authorities thereto make their respective points of view known to the other and discuss and examine the relative merits of their views. In ***Buddhadev Maity*** it was held that the whole purpose of constituting a high powered Statutory Advisory Board would be vitiated if the members appointed thereof do not get an opportunity to exchange their views with the Government and that allowing the Government to act without such fair exchange with the statutory authority would be contrary to the express language and spirit of the Act.

50. What was held by me in ***Buddhadev Maity*** supra equally applies here. The whole purpose of constitution of DTAB, DCC and setting up of Central Drugs Laboratory would be lost if it were to be held that the Central

Government, even in exercise of technical powers under Section 26A or in carrying out other functions assigned to it under the Act is not required to consult them and is free to choose the person from whom it may at that point of time take consultation. No such power has been vested under the Drugs Act with the Central Government.

51. Reference may also be made to the judgment of the Division Bench of this Court of which the undersigned was a Member in ***United Rwas Joint Action Vs. Union of India*** MANU/DE/3302/2015 (though SLP thereagainst is pending before the Supreme Court) where, in the context of Section 20 of the Comptroller and Auditor General's (Duties, Powers and Conditions of Service) Act, 1971 requiring the terms and conditions of audit to be agreed upon by the Comptroller and Auditory General (CAG) in consultation with concerned Government it was held that consultation cannot be namesake and has to be meaningful and effective. Reliance in this regard was placed on ***Mr. Justice Chandrashekaraiah (Retd.) Vs. Janekere C. Krishna*** (2013) 3 SCC 117 and ***State of Gujarat Vs. Hon'ble Mr. Justice R.A. Mehta (Retd.)*** (2013) 1 SCC 1 holding that (i) the object of consultation is to render its process meaningful, so that it may serve its intended purpose; (ii) consultation requires the meeting of minds between the parties that are

involved in the consultation process, on the basis of material facts and points, in order to arrive at a correct or at least a statutory solution; and, (iii) if certain power can be exercised only after consultation, such consultation must be conscious, effective, meaningful and purposeful; to ensure this, each party must disclose to the other, all relevant facts for due deliberation and the consultee must express his opinion only after complete consideration of the matter on the basis of the relevant facts and quintessence.

52. Once Sections 5&7 of the Drugs Act provide that the purpose of constitution of DTAB is to advice the Central Government on technical matters arising out of administration of the Act and to carry out other functions assigned to the Central Government under the Act and that the purpose of constitution of the DCC is to advice the Central Government and the DTAB on any matter tending to secure uniformity throughout India in the administration of the Act, the other provisions of the Act vesting powers in the Central Government were not required to expressly provide that the Central Government will exercise the said power with the advice of and in consultation with the DTAB and DCC. Whichsoever provision of the Drugs Act provides for exercise of powers, technical or otherwise by the Central Government, obtaining advice from and holding consultation with DTAB

and DCC would axiomatically become mandatory. Moreover the function prescribed of DTAB in Section 5 is not only to advice on technical matters but also to carry out "other functions assigned" to the Central Government under the Act. If the Central Government of its own was found fit to exercise the functions under the Act including of a technical nature and have the wherewithal therefor, there was no need for constituting the DTAB and DCC.

53. Supreme Court in ***Centre for PIL Vs. Union of India*** (2011) 4 SCC 1 reiterated that an institution is more important than an individual and an institution has to satisfy the test of values, independence, impartiality and competence and so have the persons manning the institution to satisfy the said tests. If institutions though set-up, particularly those set-up statutorily are to be bypassed, the same would severally erode the faith in the functioning of the Central Government and the decisions taken by it under the law and dent good governance and constitutional trust. Supreme Court in ***Manoj Narula Vs. Union of India*** (2014) 9 SCC 1 held that the principle of constitutional morality basically means to bow down to the norms of the Constitution and not to act in a manner which would become violative of the rule of law or reflectible of action in an arbitrary manner; it actually works at

the fulcrum and guides as a laser beam in institution building. It was held that institutional respectability and adoption of precautions for the sustenance of constitutional values would include reverence for the constitutional structure. Again in ***Board of Control for Cricket in India Vs. Cricket Association of Bihar*** (2015) 3 SCC 251 it was held that BCCI is a very important institution that discharges important public functions and demands of institutional integrity are therefore heavy and need to be met suitably in larger public interest.

54. All the emphasis laid in the judgments aforesaid on the institutions and institution building would be futile if the Central Government in exercising powers under statutes which are prescribed to be exercised on advice and in consultation with bodies/institutions also set-up under that statute were to be allowed to exercise those powers without such consultation or in consultation with other non-statutory bodies. Such statutory/public bodies/institutions perform public law function and are expected to adhere to those very standards which the law requires the Government to adhere to, as held by the Division Bench of this Court in ***Utkarsh Mandal Vs. Union of India*** MANU/DE/3078/2009 in the context of Expert Appraisal Committee under the Environment (Protection) Act, 1986. It was held that the whole purpose

of the exercise to be performed by the Expert Appraisal Committee comprising of Experts was to have a proper evaluation on the basis of objective criteria.

55. It is not as if powers under Section 26A have been exercised by the Central Government for the first time. The counsels, during the hearing cited the following judgments, in all of which the exercise of power was on advice and in consultation and/or on recommendation of DTAB/DCC:-

(i) ***Systopic Laboratiries (Pvt.) Ltd. Vs. Dr. Prem Gupta*** 1994 Supp(1) SCC 160 – the notifications of the year 1983/1988 were preceded by constitution of an expert sub-Committee by the DCC and recommendations whereof were accepted by the DCC and considered by the DTAB which recommended the ban. The representations thereagainst were also examined by the sub-Committee of DCC whose views were considered by the DTAB. It was in the aforesaid context that the Supreme Court, on challenge being made to the ban, expressed its inability to make an assessment about the relative merits of the various studies and reports placed before it (as has been done in the present case also) and held that "such an evaluation is required

to be done by the Central Government while exercising its powers under Section 26A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the DCC". Finding that the said experts in their deliberations did not consider it necessary to conduct clinical trials in respect of FDCs of steroids with bronchodilators for systematic use it was held that whether clinical trials should have been conducted or not was primarily for the experts to decide and if the experts felt that in respect of the drugs in question such clinical trials were not necessary, it is not possible to hold that there has been no proper evaluation of the material that was submitted. The contention that complete prohibition was disproportionate (as has been made before me as well) was rejected holding that "in taking this step the, Central Government appears to have moved in a cautious manner" in not immediately prohibiting the drug inspite of the view of the DCC and for the reason of the DTAB having then not agreed therewith. It was further held that while examining the reasonableness of the prohibition against manufacture and

sale of drugs, the harmful potentialities thereof have to be considered in the context of the conditions as prevalent in the country and the less drastic course of permitting manufacture and sale of the drugs with a warning about its use would not be adequate to protect the general public from the harmful consequences. The challenge was thus dismissed.

(ii) ***E. Merck (India) Ltd. Vs. Union of India*** AIR 2001 Del 326 (DB) – the challenge before the Division Bench of this Court was to the Notification dated 14th October, 1999 prohibiting certain FDCs. The impugned Notification was found to have its origin in Civil Writ Petition No. 698/1993 titled ***Drug Action Forum Vs. Union of India*** before the Supreme Court seeking action against hazardous drugs. It was found that the Supreme Court had directed the DTAB to assess the quality and nature of the of the drugs and that DTAB had constituted a technical sub-Committee for the said purpose; subsequently Supreme Court constituted a Core Group, five out of six members of which were members of DTAB and the Core Group had recommended the prohibition; the said recommendation was considered by the

DTAB which also recommended prohibition; thereafter the matter was considered by the Government and the impugned Notification issued. Dismissing the challenge it was held:-

(A) there was no merit it in the challenged to the *vires* of Section 26A;

(B) before imposition of such ban the following ingredients have to be satisfied:-

(i) satisfaction of the Central Government;

(ii) satisfaction has to relate to:-

(a) likely to involve risk to humans; or

(b) it does not have a therapeutic value; or

(c) it contains ingredients and in such quantity for which there is no therapeutic justification; and

(iii) it is necessary or expedient in public interest.

(C) the ingredients clearly spell out that the power given to the Central Government is neither uncontrolled nor unguided;

(D) a particular drug would be banned only if the Government is satisfied about its hazardous nature or nil therapeutic value, or nil therapeutic justification;

(E) above all, the Government is also to be satisfied that public interest warrants such prohibition;

(F) all these factors constitute definite guidelines to the Central Government before it acts to issue the Notification under Section 26A of the Act of prohibition;

(G) for such a provision to sustain it is not necessary that statutory appeal has to be provided - even in the absence of statutory appeal the aggrieved person has the constitutional remedy;

(H) the Scheme of the Drugs Act further provides for constitution of DTAB, Central Drugs Laboratory and DCC for the purpose of carrying out the functions assigned to it by the Act;

(I) before the Central Government records its satisfaction to prohibit the manufacture a particular drug, opinion of the DTAB and/or DCC is obtained;

(J) whenever decision of the Central Government taken under Section 26A of the Act is challenged, while exercising the power of judicial review the Court can go into the question as to whether the satisfaction was based on material, which was relevant and germane to the issue and that it was not an arbitrary exercise of power;

(K) that since the exercise undertaken was pursuant to direction issued by the Supreme Court no hearing was required to be given and the petitioners had submitted their material before the DTAB;

(L) there was thus sufficient compliance of the principles of natural justice;

(M) the Government was not under any obligation to issue show cause notice before issuance of impugned Notification;

(N) there was no merit in the contention that the impugned Notification was without any material on record as there was voluminous material before the sub-Committee of DTAB and before the Core Committee; and,

(O) the Court cannot sit in appeal against the decision of the Central Government and judicial review of such decision is available on limited grounds.

(iii) ***Uni-San Pharmaceuticals Vs. Union of India*** AIR 2002 Ker 72 – the challenge was to the Notification under Section 26A prohibiting manufacture, sale and distribution of fixed dose combination of Hydroxyquinoline group of drugs with any other drug *inter alia* on the ground that there was no consultation with the DTAB. Finding that the Notification was issued after a thorough examination by a technical sub-Committee constituted by the DTAB and on the basis of recommendation made by the DCC and with the approval of DTAB, the challenge was dismissed.

(iv) ***Drug Controller General of India Vs. West Bengal Small Scale Manufacturers Association*** AIR 2000 Cal 133 (DB) – Notification dated 13th December, 1995 under Section 26A was under challenge. Finding that before issuing the Notification the Drug Controller General of India referred the matter before the technical sub-Committee of DTAB which was held to be a

Statutory Body to advise the Central Government on the implementation of the Act and that the recommendations of the sub-Committee were accepted by the Central Government, the challenge was dismissed.

(v) ***Cipla Ltd. Vs. Union of India*** (2011) 5 CTC 640 adjudicating the challenge to the Notification dated 10th February, 2011 prohibiting manufacture and sale of phenylpropanolamine and holding that consultation with DTAB is mandatory.

(vi) ***Social Jurist, A Lawyers Group Vs. Union Of India*** (2004) 73 DRJ 578 (DB) also holding that consultation with DTAB is mandatory.

56. It would thus be seen that the challenge to the *vires* of Section 26A was rejected in ***E. Merck (India) Ltd.*** supra *inter alia* for the reason of the Act providing for exercise of power by the Central Government after obtaining the opinion of DTAB and DCC and the challenge to the Notifications earlier issued under Section 26A defeated *inter alia* for the reason of the same being on recommendation of DTAB and/or DCC. Certainly the Central Government after having the challenge to the *vires* of

Section 26A on the ground of the same vesting uncontrolled and unguided discretion in the Central Government for reasons aforesaid, bypass DTAB and DCC in exercise of power thereunder. Though the learned ASG relied on the judgment of a Single Judge of the High Court of Madras in ***Macleods Pharmaceuticals Limited Vs. Union of India*** (2012) SCC OnLine Madras 1735 and on judgment of a Single Judge of the High Court of Karnataka in ***Lundbeck India Private Limited Vs. Union of India*** (2013) SCC OnLine Kar 6622 holding such consultation with DTAB to be not mandatory but I am respectfully unable to agree with the said view. I may also notice that the Single Judge in ***Macleods Pharmaceuticals Limited*** though noticed the earlier judgment of a Single Judge of the same High Court in ***Cipla Ltd.*** supra holding to the contrary but disagreed therewith.

57. Not only so, the petitioners have also placed on record the minutes of the 68th Meeting of DTAB held on 16th February, 2015 which record that the issue of rationality of the 294 FDCs was referred to DTAB in its 56th Meeting held on 16th January, 2008 and DTAB after consideration of the matter had constituted a sub-Committee to examine the rationality of these FDCs. The minutes further record that the said 294 FDCs also were licensed without approval of the Drugs Controller and though the State Drugs

Controllers were asked to withdraw permission for their manufacture but the manufactures' Association had got stay from the High Court of Madras. The minutes further record that the sub-Committee so constituted by DTAB had examined these formulations in consultation with the manufactures' Association and stakeholders and finalised its Report and which Report was for review before the DTAB. DTAB, after consideration of the said Report recommended re-examination of some FDCs and prohibition of certain other FDCs and further recommended that the High Court of Madras be apprised thereof for vacation of stay. It thus appears that while in these proceedings it is contended that the Central Government before issuing the Notification under Section 26A was not required to consult the DTAB but has itself been seeking the advice of DTAB and acting thereon in exercise of powers thereunder. Such inconsistent stand is not understandable.

58. Section 3(h) of the Drugs Act defines patent or proprietary medicine as a drug which is not included in the edition of Indian Pharmacopoeia or any other Pharmacopoeia authorised by the Central Government after consultation with the DTAB. I am of the view that once the Central Government is not empowered to declare a drug as a patent or proprietary medicine without consultation with DTAB, so can Central Government be

not considered as empowered to declare a drug as risky or not having therapeutic value or not having therapeutic justification without consultation with the DTAB.

59. As aforesaid, the Drugs Act does not contain any regulatory mechanism for manufacture of a drug and the same has been provided under the Rules only. The Rule making power of the Central Government under Sections 12, 33 and 33N is also required to be exercised in consultation with DTAB. The proviso to Section 33 empowers the Central Government to dispense with such consultation only if the circumstances have arisen which render it necessary to make rules without such consultation but still provides for *post facto* consultation and amendment of the Rules even if framed in accordance with said consultation. The Legislature thus wherever deemed fit to empower the Central Government to dispense with such consultation, provided so.

60. I have already noticed above that under Section 16, the power to amend the Second Schedule to the Act prescribing standard of quality of drugs is also to be exercised by the Central Government in consultation with DTAB.

61. Thus, no merit is found in the contention that DTAB is not involved in the approval of the drugs. Though the Drugs Controller is constituted by the Rules as the approving authority but the parameters for approval are prescribed in consultation with the DTAB.

62. Though the respondents in their counter affidavit stated that the matter was also discussed on 24th July, 2015 at the 48th meeting of the DCC and which was refuted by the petitioners but a perusal of the minutes of the subject meeting does not bear out that the decision of the Central Government impugned in these petitions has the backing of DCC. The matter before DCC was different.

63. The respondents have also not placed before this Court any deliberations which may have been held by the Central Government on receipt of report of Kokate Committee. It is not the case of the respondents that though a report was obtained from Kokate Committee but was examined by DTAB, DCC and the Central Drugs Laboratory and they were also satisfied therewith. What thus emerges is that in the decision making process leading to the impugned notifications there was a total exclusion of DTAB, DCC and Central Drugs Laboratory and which in my view cannot be permitted.

64. It was also the contention of the learned ASG that the Federation of Pharma Entrepreneurs and other Associations of manufacturers of drugs were fully aware of the constitution of Kokate Committee, the terms of reference thereof, the scope of enquiry being undertaken by it but did not object at that time and cannot now impugn the Notifications. It was further contended that no *mala fides* have been attributed to Kokate Committee.

65. No merit is found in the aforesaid contention also. There can be no estopple against the law. Once it is found that the law i.e. the Drugs Act requires the Central Government to exercise the power under Section 26A after taking advice from and in consultation with the statutory bodies created thereunder i.e. the DTAB and DCC, the exercise of power without such advice and consultation cannot be upheld even if exercised *bona fide* and in consultation with and on advice of other experts who may be as competent as the DTAB and DCC. The maxim, what is prescribed to be done in a particular way must be done in that way and no other way, would apply. Reference if any required can be made to ***Selvi J. Jayalalithaa Vs. State of Karnataka*** (2014) 2 SCC 401, ***Mackinon Mackenzie and Company Ltd. Vs. Mackinnon Employees Union*** (2015) 4 SCC 544 and ***Zuari Cement Ltd. Vs. Regional Director E.S.I.C. Hyderabad*** (2015) 7 SCC 690 laying down

that if the procedure prescribed is not followed then such act has to be held to be null and void *ab initio* in law.

66. Importance and relevance of DTAB can also be gauged from the final decision in ***Drugs Action Forum Vs. Union of India*** supra reported as AIR SCW (2002) 2644 disposing of the petition by directing DTAB to meet at least once in six months and the Expert Committee appointed by the DTAB to look into the question of drug formulations to meet at least once in two months and to consider the suggestions made by the Drugs Action Forum from time to time. There would have been no need for such directions to be issued by the Supreme Court if the Central Government in performance of its functions under the Drugs Act was to be independent of DTAB and DCC.

67. Thus, the exercise of power by the Central Government in issuing the impugned Notifications is held to be not in consonance with the provisions of the Drugs Act. The petitions have to succeed on this ground.

68. The senior counsel for All India Drug Action Network, counsel for Veteran's Forum for Transparency in Public Life and the counsel for Wing Commander B.N.P. Singh, General Secretary of Veteran's Forum for Transparency in Public Life also opposed the petitions *inter alia* arguing that

the Government has acted on the complaints of the patients and concerned groups and that the health and safety of the patients is paramount and that the FDCs which have been banned are indeed hazardous to the patient.

69. I have already held above that this Court in exercise of power of judicial review cannot adjudicate whether these FDCs are risky to the consumers or lack therapeutic value or therapeutic justification. The statute requires the said aspects to be considered by DTAB and DCC and to report thereon. That has admittedly not been done.

70. CM No.1584/2016 in W.P.(C) No.2212/2016 was filed by Indian Medical Association (IMA) for intervention on the matter. However on enquiry from the counsel for IMA on 19th May, 2016 as to what is its stand on the matter, the counsel stated that IMA was supporting the impugned Notifications and opposing the petitions. However on further enquiry as to how a decision to oppose the petitions had been taken, whether by holding a franchise of all members of IMA, the counsel stated that he will have to obtain instructions and could only state that President of IMA had taken the decision. However on further enquiry as to the authority of the President of IMA to take such a decision time was sought to obtain instructions. Thereafter the counsel for IMA did not appear. The opinion of the members

of IMA being the medical practitioners administering the FDCs subject matter of these petitions would though have thrown light on the parameters on which power under Section 26A is to be exercised.

71. Though at one stage of the hearing I had expressed doubts as to the locus of the Federation of Pharma Entrepreneurs to maintain W.P.(C) No.2500/2016 impugning all 344 Notifications but the senior counsels for the petitioners had referred to plethora of case law thereon. Need however to go into the said aspect is not felt in view of the reasoning hereinabove and for which alone the petitions are entitled to succeed.

72. Before parting with this subject, for the sake of completeness I may record that CDSCO is not a Statutory Authority under the Drugs Act. Its website www.cdsco.nic.in describes it as the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs Act, with Drugs Controller at its helm. Interestingly, the Drugs Controller is not an office established under the Drugs Act; rather Section 5 of the Act prescribes the DTAB to be having the Drugs Controller as its ex-officio member. Rule 2(b) defines the Central Licence Approving Authority as the Drugs Controller appointed by the Central Government.

73. In view my findings above, there is no need to go into the other aspects on which arguments were urged. I may however record my musings thereon.

74. I had during the hearing enquired as to in exercise of which power the Central Government had constituted the Kokate Committee to look into the applications which were received for approval of FDCs from the Central Government. Under Rule 21(b), the powers of Licensing Authority have been vested in the Drugs Controller and not the Central Government. I am of the view that once the Central Government had directed the SLAs to direct the manufacturers who had obtained licences from them between September, 1988 and October, 2012 for manufacture of FDCs without having the approval of the Drugs Controller thereof as a new drug, to make applications therefor, such applications could have been considered by the Drugs Controller only and none of the provisions of the Act empower the Central Government to nominate Kokate Committee or any other committee or person as the Licensing Authority. However need to render any final decision on the said aspect is not felt as in pursuance to the Report of the Kokate Committee the applications have not been dealt with. Moreover,

there is a provision for appeal against the decision of the Drugs Controller on an application.

75. There were considerable arguments on the aspect of the need for grant of a hearing before exercise of powers under Section 26A with respect to a drug already in use. Though in view of the above there is no need to render any final decision thereon but I may highlight that Section 16(2) of the Drugs Act, while empowering the Central Government to amend Schedule –II to the Act prescribing the standards of quality, requires the same to be done with a three months notice of intention to do so. It appears that once amendment of the Schedule prescribing standards of quality (and which may render a drug already in use as not of standard quality and resultantly require its manufacture to be stopped) is prescribed to be done after three months notice, so should ordinarily the power under Section 26A be exercised after giving notice to the persons who have already been granted permissions to manufacture the said drug unless there is grave urgency and for which reason should be recorded. Suffice it is to state that the manner in which the proceedings till the issuance of the Notification have gone, does not suggest any such grave urgency.

76. To say the least, the Central Government, though acting in public interest, seems to have gone about it in a haphazard manner. It claims that the FDCs for manufacture of which licences were issued by SLAs between September, 1988 and 1st October, 2012 without the same having approval of the Drugs Controller were wrongly granted such licences. However instead of taking action for cancellation of said licences, the manufactures were asked to apply for licences to be Drugs Controller, while continuing to manufacture the drugs for which according to the Central Government licence was wrongly given. When such applications were received, instead of the same being considered by the Drugs Controller, who is vested with the power of approval, ten committees were constituted for considering the applications. After the said committees failed to examine all the applications, the Kokate Committee was constituted. The said Kokate Committee, instead of considering the applications for approval, went into the aspects of risk to consumers and therapeutic value and therapeutic justification and on receiving report whereof impugned Notifications were issued.

77. Though the learned ASG controverted that any opportunity of hearing is required to be given before exercise of power under Section 26A but as the aforesaid narrative would show, the Central Government claims to have

issued show cause notices after receipt of report of Kokate Committee and replies thereto having also been considered by the Kokate Committee.

78. The petitions thus succeed. All 344 Notifications dated 10th March, 2016 purportedly in exercise of power under section 26A of the Drugs Act are found to have been issued without following the procedure statutorily prescribed to be followed prior to issuance thereof and resultantly it is held that the Notifications are not based on satisfaction of the Central Government prescribed to be on the advice of an in consultation with the DTAB and DCC. Resultantly the said Notifications are quashed.

79. The petitions are disposed of.

80. No costs.

RAJIV SAHAI ENDLAW, J.

DECEMBER 1, 2016
'bs/gsr/pp'

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% **Date of decision: 1st December, 2016.**

\+ **W.P.(C) No.2212/2016**

PFIZER LIMITED & ANR ..... Petitioners

Versus

UNION OF INDIA & ANR ..... Respondents

AND 453 OTHER PETITIONS

(SCHEDULE)

1	W.P.(C) 2213/2016	ABBOTT HEALTHCARE PVT LTD & ANR. VS. UNION OF INDIA & ANR
2	W.P.(C) 2214/2016	ABBOTT HEALTHCARE PVT LTD & ANR. VS. UNION OF INDIA & ANR
3	W.P.(C) 2231/2016	MACLEODS PHARMACEUTICALS LTD. VS. DURGS CONTROLLER GENERAL OF INDIA & ANR
4	W.P.(C) 2258/2016	RECKITT BENCKISER HEALTHCARE (INDIA) PVT. LTD. VS. UNION OF INDIA & ANR
5	W.P.(C) 2264/2016	PROCTER & GAMBLE HYGIENE & HEALTHCARE LIMITED VS. UNION OF INDIA & ANR
6	W.P.(C) 2265/2016	ALEMBIC PHARMACEUTICALS LIMITED VS. DURGS CONTROLLER GENERAL OF INDIA & ANR
7	W.P.(C) 2266/2016	GLENMARK PHARMACEUTICALS LIMITED & ANR. VS. UNION OF INDIA & ANR
8	W.P.(C) 2267/2016	GLENMARK PHARMACEUTICALS LIMITED & ANR. VS. UNION OF INDIA & ANR
9	W.P.(C) 2268/2016	GLENMARK PHARMACEUTICALS LIMITED & ANR. VS. UNION OF INDIA & ANR

10	W.P.(C) 2269/2016	PIRAMAL ENTERPRISES LTD. VS. UNION OF INDIA & ANR
11	W.P.(C) 2272/2016	ALEMBIC PHARMACEUTICALS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
12	W.P.(C) 2273/2016	ALEMBIC PHARMACEUTICALS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
13	W.P.(C) 2274/2016	GLENMARK PHARMACEUTICALS LIMITED & ANR. VS. UNION OF INDIA & ANR
14	W.P.(C) 2285/2016	LABORATE PHARMACEUTICALS INDIA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
15	W.P.(C) 2286/2016	LABORATE PHARMACEUTICALS INDIA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
16	W.P.(C) 2288/2016	LABORATE PHARMACEUTICALS INDIA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
17	W.P.(C) 2298/2016	WOCKHARDT LIMITED VS. UNION OF INDIA & ANR
18	W.P.(C) 2333/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
19	W.P.(C) 2334/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
20	W.P.(C) 2336/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
21	W.P.(C) 2337/2016	CIPLA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ORS
22	W.P.(C) 2338/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
23	W.P.(C) 2339/2016	AJANTA PHARMA LIMITED & ANR VS. UNION OF INDIA & ANR
24	W.P.(C) 2340/2016	CIPLA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ORS

25	W.P.(C) 2341/2016	CIPLA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ORS
26	W.P.(C) 2342/2016	CIPLA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ORS
27	W.P.(C) 2343/2016	DR. REDDY'S LABORATORIES LTD. & ANR VS. UNION OF INDIA & ORS
28	W.P.(C) 2344/2016	FDC LIMITED & ANR VS. UNION OF INDIA & ANR
29	W.P.(C) 2345/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
30	W.P.(C) 2346/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
31	W.P.(C) 2347/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
32	W.P.(C) 2348/2016	CORAL LABORATORIES LIMITED & ANR VS. UNION OF INDIA & ANR
33	W.P.(C) 2349/2016	CIPLA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ORS
34	W.P.(C) 2350/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
35	W.P.(C) 2351/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
36	W.P.(C) 2352/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
37	W.P.(C) 2353/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
38	W.P.(C) 2354/2016	AJANTA PHARMA LIMITED & ANR VS. UNION OF INDIA & ANR
39	W.P.(C) 2355/2016	CIPLA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ORS

40	W.P.(C) 2356/2016	KHANDELWAL LABORATORIES PVT. LTD. VS. UNION OF INDIA
41	W.P.(C) 2368/2016	WOCKHARDT LIMITED & ANR VS. UNION OF INDIA & ANR
42	W.P.(C) 2369/2016	MANKIND PHARMA LIMITED & ORS VS. UNION OF INDIA & ANR
43	W.P.(C) 2370/2016	ERIS LIFESCIENCES PRIVATE LIMITED VS. UNION OF INDIA & ANR
44	W.P.(C) 2371/2016	MANKIND PHARMA LIMITED & ORS VS. UNION OF INDIA & ANR
45	W.P.(C) 2372/2016	MANKIND PHARMA LIMITED & ORS VS. UNION OF INDIA & ANR
46	W.P.(C) 2373/2016	MANKIND PHARMA LIMITED & ORS VS. UNION OF INDIA & ANR
47	W.P.(C) 2374/2016	MANKIND PHARMA LIMITED & ORS VS. UNION OF INDIA & ANR
48	W.P.(C) 2375/2016	WOCKHARDT LIMITED VS. UNION OF INDIA & ANR
49	W.P.(C) 2376/2016	GLAXOSMITHKLINE PHARMACEUTICALS LTD. & ANR VS. UNION OF INDIA & ANR
50	W.P.(C) 2378/2016	LUPIN LIMITED & ANR VS. UNION OF INDIA & ANR
51	W.P.(C) 2379/2016	LUPIN LIMITED & ANR VS. UNION OF INDIA & ANR
52	W.P.(C) 2380/2016	ERIS LIFESCIENCES PRIVATE LTD. VS. UNION OF INDIA & ANR
53	W.P.(C) 2384/2016	GLAXO SMITHKLINE ASIA PVT LTD & ANR. VS. UNION OF INDIA & ORS
54	W.P.(C) 2385/2016	M/S LABORATOIRES GRIFFON PVT. LTD. & ANRS. VS. UNION OF INDIA & ORS

55	W.P.(C) 2404/2016	CENTAUR PHARMACEUTICALS PVT. LTD. VS. UNION OF INDIA & ANR
56	W.P.(C) 2405/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
57	W.P.(C) 2407/2016	ALEMBIC PHARMACEUTICALS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
58	W.P.(C) 2408/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
59	W.P.(C) 2409/2016	M/S SYSTOPIC LABORATORIES PVT. LTD. & ANR VS. UNION OF INDIA & ANR
60	W.P.(C) 2410/2016	KHANDELWAL LABORATORIES PVT LTD. VS. UNION OF INDIA
61	W.P.(C) 2411/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
62	W.P.(C) 2412/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
63	W.P.(C) 2413/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
64	W.P.(C) 2419/2016	MANKIND PHARMA LIMITED & ORS Vs. UNION OF INDIA & ANR
65	W.P.(C) 2425/2016	M/S GENO PHARMACEUTICALS PVT LIMITED & ANR. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
66	W.P.(C) 2426/2016	M/S GENO PHARMACEUTICALS PVT LIMITED & ANR. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
67	W.P.(C) 2427/2016	UNICHEM LABORATORIES LIMITED & ANR. VS. UNION OF INDIA & ANR.
68	W.P.(C) 2428/2016	M/S GENO PHARMACEUTICALS PVT LIMITED & ANR. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
69	W.P.(C) 2429/2016	SHREYA LIFE SCIENCES PVT LTD VS. UNION OF INDIA & ANR.

70	W.P.(C) 2430/2016	LUPIN LIMITED & ANR Vs. UNION OF INDIA & ANR
71	W.P.(C) 2431/2016	M/S GENO PHARMACEUTICALS PVT LIMITED & ANR. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
72	W.P.(C) 2432/2016	M/S GENO PHARMACEUTICALS PVT LIMITED & ANR. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
73	W.P.(C) 2433/2016	M/S GENO PHARMACEUTICALS PVT LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
74	W.P.(C) 2434/2016	LUPIN LIMITED & ANR VS. UNION OF INDIA & ANR
75	W.P.(C) 2436/2016	M/S GENO PHARMACEUTICALS PVT LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
76	W.P.(C) 2437/2016	M/S GENO PHARMACEUTICALS PVT LIMITED & ANR. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
77	W.P.(C) 2438/2016	GLENMARK PHARMACEUTICALS LIMITED & ANR. VS. UNION OF INDIA & ANR
78	W.P.(C) 2453/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
79	W.P.(C) 2483/2016	SANOFI INDIA LTD. & ANR VS. UNION OF INDIA & ANR
80	W.P.(C) 2484/2016	INGA LABORATORIES PRIVATE LTD. & ANR. VS. UNION OF INDIA & ANR
81	W.P.(C) 2485/2016	LA PRISTINE BIOEUTICALS PVT. LTD. VS. UNION OF INDIA & ANR
82	W.P.(C) 2486/2016	LABORATE PHARMACEUTICALS INDIA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
83	W.P.(C) 2488/2016	KEMWELL BIOPHARMA PVT LTD & ANR. VS. UNION OF INDIA & ANR
84	W.P.(C) 2490/2016	LABORATE PHARMACEUTICALS INDIA LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR

85	W.P.(C) 2492/2016	OMNI PROTECH DRUGS PVT LTD & ANR VS. UNION OF INDIA & ANR
86	W.P.(C) 2493/2016	VITAL THERAPEUTICS & FORMULATIONS PVT LTD & ANR VS. UNION OF INDIA & ANR
87	W.P.(C) 2500/2016	FEDERATION OF PHARMA ENTERPRENEURS & ANR VS. UNION OF INDIA & ANR
88	W.P.(C) 2511/2016	EMCURE PHARMACEUTICALS LIMITED & ANR. VS. UNION OF INDIA & ANR
89	W.P.(C) 2532/2016	M/S ACCENT PHARMA & ORS VS. UNION OF INDIA & ANR
90	W.P.(C) 2533/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
91	W.P.(C) 2534/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
92	W.P.(C) 2535/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
93	W.P.(C) 2536/2016	TORRENT PHARMACEUTICALS LIMITED VS. UNION OF INDIA & ANR
94	W.P.(C) 2537/2016	M/S LEEFOLD HEALTHCARE LTD. VS. UNION OF INDIA & ANR
95	W.P.(C) 2538/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
96	W.P.(C) 2539/2016	STANDARD PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
97	W.P.(C) 2541/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
98	W.P.(C) 2542/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
99	W.P.(C) 2543/2016	TABLETS (INDIA) LIMITED & ANR. VS. UNION OF INDIA & ANR

100	W.P.(C) 2544/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
101	W.P.(C) 2545/2016	TORRENT PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
102	W.P.(C) 2546/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
103	W.P.(C) 2547/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
104	W.P.(C) 2548/2016	M/S SYSTOPIC LABORATORIES PVT LTD. & ANR. VS. UNION OF INDIA
105	W.P.(C) 2553/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
106	W.P.(C) 2555/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
107	W.P.(C) 2556/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
108	W.P.(C) 2558/2016	IND SWIFT LTD VS. UNION OF INDIA & ANR
109	W.P.(C) 2595/2016	M/S LABORATOIRES GRIFFON PVT. LTD. & ANR. VS. UNION OF INDIA & ORS
110	W.P.(C) 2599/2016	PHARMED LIMITED & ORS. VS. UNION OF INDIA & ANR
111	W.P.(C) 2618/2016	ENTOD PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
112	W.P.(C) 2621/2016	RUBY ORGANICS PRIVATE LIMITED & ORS VS. UNION OF INDIA & ANR
113	W.P.(C) 2622/2016	AKUMS DRUGS & PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
114	W.P.(C) 2623/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR

115	W.P.(C) 2625/2016	M/S. NEM LABORATORIES PVT. LTD. VS. UNION OF INDIA & ORS
116	W.P.(C) 2626/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
117	W.P.(C) 2627/2016	ARISTO PHARMACEUTICALS LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
118	W.P.(C) 2630/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
119	W.P.(C) 2631/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR
120	W.P.(C) 2632/2016	M/S ARISTO PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
121	W.P.(C) 2633/2016	M/S ARISTO PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
122	W.P.(C) 2634/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR
123	W.P.(C) 2636/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
124	W.P.(C) 2637/2016	ERIS LIFESCIENCES PRIVATE LIMITED VS. UNION OF INDIA & ANR
125	W.P.(C) 2638/2016	FDC LIMITED & ANR VS. UNION OF INDIA & ANR
126	W.P.(C) 2639/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
127	W.P.(C) 2643/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR
128	W.P.(C) 2644/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR
129	W.P.(C) 2666/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR

130	W.P.(C) 2667/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
131	W.P.(C) 2676/2016	COMED CHEMICALS LTD & ANR VS. UNION OF INDIA & ANR
132	W.P.(C) 2677/2016	MANKIND PHARMA LTD & ORS VS. UNION OF INDIA & ANR
133	W.P.(C) 2678/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
134	W.P.(C) 2679/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
135	W.P.(C) 2680/2016	ALKEM LABORATORIES LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
136	W.P.(C) 2682/2016	VIVIMED LABS LIMITED & ANR VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
137	W.P.(C) 2683/2016	MERCK LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
138	W.P.(C) 2689/2016	M/S BIOLOGICAL E LTD. & ANR VS. UNION OF INDIA & ANR
139	W.P.(C) 2697/2016	ZEE LABORATORIES LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
140	W.P.(C) 2698/2016	COPPER PHARMA LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
141	W.P.(C) 2703/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR
142	W.P.(C) 2709/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR
143	W.P.(C) 2713/2016	VARAV BIOGENESIS PVT LTD & ANR. VS. UNION OF INDIA & ANR
144	W.P.(C) 2714/2016	M/S. INDOCO REMEDIES LTD. & ANR. VS. UNION OF INDIA & ANR

145	W.P.(C) 2715/2016	VARAV BIOGENESIS PVT LTD & LTD. VS. UNION OF INDIA & ANR
146	W.P.(C) 2716/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR
147	W.P.(C) 2717/2016	VARAV BIOGENESIS PVT LTD & LTD. VS. UNION OF INDIA & ANR
148	W.P.(C) 2718/2016	VARAV BIOGENESIS PVT LTD & LTD. VS. UNION OF INDIA & ANR
149	W.P.(C) 2719/2016	VARAV BIOGENESIS PVT LTD & LTD. VS. UNION OF INDIA & ANR
150	W.P.(C) 2720/2016	VARAV BIOGENESIS PVT LTD & LTD. VS. UNION OF INDIA & ANR
151	W.P.(C) 2721/2016	VARAV BIOGENESIS PVT LTD & LTD. VS. UNION OF INDIA & ANR
152	W.P.(C) 2722/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR
153	W.P.(C) 2727/2016	ZEN LABS INDIA & ORS VS. UNION OF INDIA & ANR
154	W.P.(C) 2733/2016	ZOTA HEALTHCARE LIMITED VS. UNION OF INDIA & ANR
155	W.P.(C)2762/2016	LINCOLN PHARMACEUTICALS LIMITED & ANR VS. UNION OF INDIA & ANR
156	W.P.(C) 2763/2016	PSYCHOTROPICS INDIA LIMITED VS. UNION OF INDIA & ANR
157	W.P.(C) 2764/2016	LINCOLN PHARMACEUTICALS LIMITED & ORS VS. UNION OF INDIA & ANR
158	W.P.(C) 2765/2016	CORONA REMEDIES PRIVATE LIMITED & ORS VS. UNION OF INDIA & ANR
159	W.P.(C) 2777/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR

160	W.P.(C) 2778/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR
161	W.P.(C) 2779/2016	HORIZON BIOCEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
162	W.P.(C) 2780/2016	HORIZON BIOCEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
163	W.P.(C) 2781/2016	HORIZON BIOCEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
164	W.P.(C) 2782/2016	HORIZON BIOCEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
165	W.P.(C) 2783/2016	HORIZON BIOCEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ORS
166	W.P.(C) 2784/2016	HORIZON BIOCEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
167	W.P.(C) 2785/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR
168	W.P.(C) 2786/2016	VARAV BIOGENESIS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
169	W.P.(C) 2787/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR
170	W.P.(C) 2788/2016	HORIZON BIOCEUTICALS PVT LTD. & ANR VS. UNION OF INDIA & ANR
171	W.P.(C) 2789/2016	HORIZON BIOCEUTICALS PVT LTD & ANR VS. UNION OF INDIA & ANR
172	W.P.(C) 2834/2016	M/S WINGS PHARMACEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA
173	W.P.(C) 2843/2016	M/S WINGS PHARMACEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA
174	W.P.(C) 2863/2016	J.B. CHEMICALS & PHARMACEUTICALS LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR

175	W.P.(C) 2864/2016	J.B. CHEMICALS & PHARMACEUTICALS LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
176	W.P.(C) 2865/2016	J.B. CHEMICALS & PHARMACEUTICALS LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
177	W.P.(C) 2867/2016	J.B. CHEMICALS & PHARMACEUTICALS LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
178	W.P.(C) 2884/2016	M/S WINGS PHARMACEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA
179	W.P.(C) 2915/2016	MACLEODS PHARMACEUTICALS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
180	W.P.(C) 2942/2016	M/S TRIKO PHARMACEUTICALS VS. UNION OF INDIA
181	W.P.(C) 2968/2016	AMTEX PHARMA PVT LTD & ANR VS. UNION OF INDIA & ANR
182	W.P.(C) 2971/2016	ANTEX PHARMA PVT LTD & ANR VS. UNION OF INDIA & ANR
183	W.P.(C) 2984/2016	M/S TRIKO PHARMACEUTICALS VS. UNION OF INDIA
184	W.P.(C) 3009/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
185	W.P.(C) 3046/2016	ANTEX PHARMA PRIVATE LIMITED VS. UNION OF INDIA & ANR
186	W.P.(C) 3053/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
187	W.P.(C) 3056/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
188	W.P.(C) 3057/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
189	W.P.(C) 3058/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR

190	W.P.(C) 3063/2016	USV PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
191	W.P.(C) 3095/2016	RUSSIAN REMEDIES (DIVISION OFANTEX PHARMA PVT LTD) VS. UNION OF INDIA & ANR
192	W.P.(C) 3096/2016	RUSSIAN REMEDIES (DIVISION OFANTEX PHARMA PVT LTD) VS. UNION OF INDIA & ANR
193	W.P.(C) 3098/2016	RUSSIAN REMEDIES (DIVISION OFANTEX PHARMA PVT LTD) VS. UNION OF INDIA & ANR
194	W.P.(C) 3100/2016	RUSSIAN REMEDIES (DIVISION OFANTEX PHARMA PVT LTD) VS. UNION OF INDIA & ANR
195	W.P.(C) 3102/2016	RUSSIAN REMEDIES (DIVISION OFANTEX PHARMA PVT LTD) VS. UNION OF INDIA & ANR
196	W.P.(C) 3120/2016	HETERO HEALTHCARE LTD & ANR VS. UNION OF INDIA & ANR
197	W.P.(C) 3160/2016	WOCKHARDT LIMITED VS. UNION OF INDIA & ANR
198	W.P.(C) 3171/2016	AEON FORMULATIONS PVT. LTD VS. UNION OF INDIA & ANR
199	W.P.(C) 3172/2016	M/S SUNGLOW PHARMACEUTICALS PVT. LTD. VS. UNION OF INDIA & ANR
200	W.P.(C) 3173/2016	FOURRTS (INDIA) LABORATORIS PVT. LTD. VS. UNION OF INDIA & ANR
201	W.P.(C) 3175/2016	INDCHEMIE HEALTH SPECIALITIES PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
202	W.P.(C) 3176/2016	INDCHEMIE HEALTH SPECIALITIES PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
203	W.P.(C) 3177/2016	AKUMS DRUGS & PHARMACEUTICALS LIMITED VS. UNION OF INDIA & ANR
204	W.P.(C) 3178/2016	INDCHEMIE HEALTH SPECIALITIES PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR

205	W.P.(C) 3179/2016	BLUE CROSS LABORATORIES PRIVATE LTD & ANR VS. UNION OF INDIA & ANR
206	W.P.(C) 3180/2016	INDCHEMIE HEALTH SPECIALITIES PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
207	W.P.(C) 3189/2016	BLUE CROSS LABORATORIES PRIVATE LTD & ANR VS. UNION OF INDIA & ANR
208	W.P.(C) 3227/2016	M/S SRISHTI BIOTEC VS. UNION OF INDIA & ANR
209	W.P.(C) 3228/2016	M/S SKAN RESEARCH LAB (P) LTD. VS. UNION OF INDIA & ANR
210	W.P.(C) 3229/2016	MACLEODS PHARMACEUTICALS LIMITED VS. DRUG CONTROLLER GENERAL OF INDIA & ANR
211	W.P.(C) 3232/2016	M/S SRISHTI BIOTEC VS. UNION OF INDIA & ANR
212	W.P.(C) 3233/2016	M/S SKAN RESEARCH LAB (P) LTD. VS. UNION OF INDIA & ANR
213	W.P.(C) 3234/2016	M/S SKAN RESEARCH LAB (P) LTD. VS. UNION OF INDIA & ANR
214	W.P.(C) 3238/2016	M/S SKN ORGANICS (P) LTD. VS. UNION OF INDIA & ANR
215	W.P.(C) 3239/2016	M/S SKAN RESEARCH LAB PVT. LTD. VS. UNION OF INDIA & ANR
216	W.P.(C) 3240/2016	M/S SKAN RESEARCH LAB (P) LTD. VS. UNION OF INDIA & ANR
217	W.P.(C) 3243/2016	M/S SKN ORGANICS PVT. LTD. VS. UNION OF INDIA & ANR
218	W.P.(C) 3247/2016	CACHET PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
219	W.P.(C) 3250/2016	CACHET PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR

220	W.P.(C) 3251/2016	CACHET PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
221	W.P.(C) 3252/2016	M/S MEDICHEM ENTERPRISES & ANR VS. UNION OF INDIA & ANR
222	W.P.(C) 3253/2016	MEPROHAX LIFESCIENCES PRIVATE LIMITED VS. UNION OF INDIA & ANR
223	W.P.(C) 3254/2016	MACLEODS PHARMACEUTICALS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
224	W.P.(C) 3255/2016	MACMILLON PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
225	W.P.(C) 3257/2016	BIOCON LTD. & ANR VS. UNION OF INDIA & ANR
226	W.P.(C) 3259/2016	HEMA LABORATORIES PRIVATE LIMITED VS. UNION OF INDIA & ANR
227	W.P.(C) 3261/2016	SAHIL MAHAJAN VS. UNION OF INDIA & ANR
228	W.P.(C) 3262/2016	KOYE PHARMACEUTICALS PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
229	W.P.(C) 3263/2016	VIVIMED LABS LIMITED & ANR VS. UNION OF INDIA & ANR
230	W.P.(C) 3264/2016	CACHET PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
231	W.P.(C) 3266/2016	CACHET PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
232	W.P.(C) 3268/2016	CONFEDERATION OF INDIAN INDIA PHARMACEUTICAL INDUSTRY (SSI) VS. UNION OF INDIA & ANR
233	W.P.(C) 3335/2016	WANBURY LIMITED & ANR VS. UNION OF INDIA
234	W.P.(C) 3341/2016	WANBURY LIMITED & ANR VS. UNION OF INDIA

235	W.P.(C) 3642/2016	BIOSEARCH ORGANICS VS. UNION OF INDIA & ANR
236	W.P.(C) 3770/2016	GENX PHARMA LIMITED & ORS VS. UNION OF INDIA & ANR
237	W.P.(C) 3781/2016	HETERO HEALTHCARE LTD. & ORS VS. UNION OF INDIA & ANR
238	W.P.(C) 3814/2016	MEDSOL INDIA OVERSEAS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
239	W.P.(C) 3851/2016	M/S LARK LABORATORIES INDIA LTD. & ANR VS. UNION OF INDIA & ANR
240	W.P.(C) 3856/2016	ACRON PHARMACEUTICALS VS. UNION OF INDIA & ANR
241	W.P.(C) 3862/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ANR. VS. UNION OF INDIA & ANR
242	W.P.(C) 3863/2016	M/S UNICURE INDIA LTD. VS. UNION OF INDIA & ANR
243	W.P.(C) 3864/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
244	W.P.(C) 3865/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
245	W.P.(C) 3869/2016	SOMATICO PHARMACAL PVT. LTD. VS. UNION OF INDIA & ANR
246	W.P.(C) 3870/2016	M/S OBSURGE BIOTECH LTD. VS. UNION OF INDIA & ANR
247	W.P.(C) 3871/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ANR VS. UNION OF INDIA & ANR
248	W.P.(C) 3901/2016	PHARMA SYNTH FORMULATIONS LTD. VS. UNION OF INDIA & ANR
249	W.P.(C) 3902/2016	OZONE PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR

250	W.P.(C) 3903/2016	SEAGULL LABORATORIES (I) P. LTD. VS. UNION OF INDIA & ANR
251	W.P.(C) 3904/2016	SEAGULL LABORATORIES (I) P. LTD. VS. UNION OF INDIA & ANR
252	W.P.(C) 3905/2016	OZONE PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
253	W.P.(C) 3907/2016	SUN PHARMACEUTICALS INDUSTRIES LTD. & ANR VS. UNION OF INDIA & ANR
254	W.P.(C) 3917/2016	APEX LABORATORIES PRIVATE LIMITED VS. UNION OF INDIA & ANR
255	W.P.(C) 3920/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ORS VS. UNION OF INDIA & ANR
256	W.P.(C) 3923/2016	RIVPRA FORMULATION PRIVATE LIMITED & ANR VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
257	W.P.(C) 3928/2016	DAKSH PHARMACEUTICALS PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
258	W.P.(C) 3930/2016	ORDAIN HEALTHCARE GLOBAL PRIVATE LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
259	W.P.(C) 3936/2016	REGENT AJANTA BIOTECH VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
260	W.P.(C) 3937/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ORS VS. UNION OF INDIA & ANR
261	W.P.(C) 3938/2016	M/S SEAGULL PHARMACEUTICAL PVT. LTD. VS. UNION OF INDIA & ANR
262	W.P.(C) 3939/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ORS VS. UNION OF INDIA & ANR
263	W.P.(C) 3940/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ORS VS. UNION OF INDIA & ANR
264	W.P.(C) 3942/2016	AKMUS DRUGS & PHARMACEUTICALS LIMITED VS. UNION OF INDIA & ANR

265	W.P.(C) 3957/2016	CENTAUR PHARMACEUTICALS PVT. LTD. & ORS VS. UNION OF INDIA & ANR
266	W.P.(C) 3963/2016	M/S MICRO LABS LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
267	W.P.(C) 3964/2016	SAMSON LABORATORIES PVT. LTD. VS. UNION OF INDIA & ANR
268	W.P.(C) 3965/2016	MED MANOR ORGANICS PVT. LTD. VS. UNION OF INDIA & ANR
269	W.P.(C) 3979/2016	SUN PHARMACEUTICALS INDUSTRIES LTD. & ANR VS. UNION OF INDIA & ANR
270	W.P.(C) 3980/2016	MERIDIAN MEDICARE LIMITED VS. UNION OF INDIA & ANR
271	W.P.(C) 3981/2016	JENBURKT PHARMACEUTICALS LTD. & ANR VS. UNION OF INDIA & ANR
272	W.P.(C) 3982/2016	ELAN PHARMA (INDIA) PVT. LTD. VS. UNION OF INDIA & ANR
273	W.P.(C) 3990/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
274	W.P.(C) 3991/2016	INTAS PHARMACEUTICALS LIMITED & ANR VS. UNION OF INDIA & ANR
275	W.P.(C) 3993/2016	JENBURKT PHARMACEUTICALS LTD. & ANR VS. UNION OF INDIA & ANR
276	W.P.(C) 3994/2016	JENBURKT PHARMACEUTICALS LTD. & ANR VS. UNION OF INDIA & ANR
277	W.P.(C) 3996/2016	INTAS PHARMACEUTICALS LIMITED & ANR VS. UNION OF INDIA & ANR
278	W.P.(C) 3997/2016	INTAS PHARMACEUTICALS LIMITED & ANR VS. UNION OF INDIA & ANR
279	W.P.(C) 3999/2016	M/S MEDOPHARM VS. UNION OF INDIA & ANR

280	W.P.(C) 4000/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
281	W.P.(C) 4001/2016	JENBURKT PHARMACEUTICALS LTD. & ANR VS. UNION OF INDIA & ANR
282	W.P.(C) 4006/2016	INTAS PHARMACEUTICALS LIMITED & ANR VS. UNION OF INDIA & ANR
283	W.P.(C) 4007/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
284	W.P.(C) 4041/2016	REXCIN PHARMACEUTICAL PVT. LTD. & ANR VS. UNION OF INDIA & ANR
285	W.P.(C) 4046/2016	M/S SALUTE BESTOCHEM & ANR VS. UNION OF INDIA
286	W.P.(C) 4051/2016	M/S SALUTE BESTOCHEM & ANR VS. UNION OF INDIA
287	W.P.(C) 4052/2016	M/S SALUTE BESTOCHEM & ANR VS. UNION OF INDIA
288	W.P.(C) 4063/2016	M/S UNIVERSAL TWIN LABS VS. UNION OF INDIA
289	W.P.(C) 4064/2016	M/S UNIVERSAL TWIN LABS VS. UNION OF INDIA
290	W.P.(C) 4073/2016	M/S SALUTE BESTOCHEM & ANR VS. UNION OF INDIA
291	W.P.(C) 4074/2016	M/S SALUTE BESTOCHEM & ANR VS. UNION OF INDIA
292	W.P.(C) 4105/2016	PURO PHARMA LABORATORIES VS. UNION OF INDIA & ANR
293	W.P.(C) 4107/2016	NAVIL LABORATORIES VS. UNION OF INDIA & ANR
294	W.P.(C) 4108/2016	CHINUBHAI PHARMA PVT. LTD. & ANR VS. UNION OF INDIA & ANR

295	W.P.(C) 4115/2016	LINCOLN PARENTERAL LIMITED VS. UNION OF INDIA & ANR
296	W.P.(C) 4139/2016	GUJARAT TERCE LABORATORIES LIMITED & ANR VS. UNION OF INDIA & ANR
297	W.P.(C) 4148/2016	TIDAL LABORATORIES PVT. LTD. VS. UNION OF INDIA & ANR
298	W.P.(C) 4188/2016	DALLAS FORMILATIONS PVT. LTD. VS. UNION OF INDIA & ANR
299	W.P.(C) 4205/2016	OZONE PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
300	W.P.(C) 4207/2016	M/S CREATIVE HEALTHCARE PVT. LTD. VS. UNION OF INDIA & ANR
301	W.P.(C) 4216/2016	OZONE PHARMACEUTICALS LTD. VS. UNION OF INDIA & ANR
302	W.P.(C) 4236/2016	TORQUE PHARMACEUTICALS PRIVATE LIMITED VS. UNION OF INDIA & ANR
303	W.P.(C) 4239/2016	M/S CHIMAK HEALTH CARE VS. UNION OF INDIA & ANR
304	W.P.(C) 4240/2016	M/S INNOVA CAPTAB VS. UNION OF INDIA & ANR
305	W.P.(C) 4245/2016	M/S D M PHARMA VS. UNION OF INDIA & ANR
306	W.P.(C) 4247/2016	KUSUM HEALTHCARE P. LTD VS. UNION OF INDIA & ANR
307	W.P.(C) 4248/2016	M/S. AUSTRO LABS LTD. VS. UNION OF INDIA & ANR
308	W.P.(C) 4257/2016	CURETECH SKINCARE VS. UNION OF INDIA & ANR
309	W.P.(C) 4262/2016	INNOVA CAPTAB PRIVATE LIMITED VS. UNION OF INDIA & ANR

310	W.P.(C) 4263/2016	M/S CHIROS PHARMA VS. UNION OF INDIA & ANR
311	W.P.(C) 4264/2016	BIOCHEMIX HEALTHCARE PVT LTD VS. UNION OF INDIA & ANR
312	W.P.(C) 4265/2016	M/S SUNDYOTA NUMANDIS PHARMACEUTICALS P LTD & ANR VS. UNION OF INDIA & ANR
313	W.P.(C) 4266/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
314	W.P.(C) 4267/2016	YASH PHARMA LABORATORIES PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
315	W.P.(C) 4270/2016	SKYMAP PHARMACEUTICALS PRIVATE LIMITED VS. UOI & ANR
316	W.P.(C) 4272/2016	UNIBIOTECH FORMULATION VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
317	W.P.(C) 4273/2016	KASH MEDICARE PVT LTD VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
318	W.P.(C) 4274/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
319	W.P.(C) 4282/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
320	W.P.(C) 4288/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
321	W.P.(C) 4289/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
322	W.P.(C) 4290/2016	RPG LIFE SCIENCES LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
323	W.P.(C) 4291/2016	M/S HAB PHARMACEUTICALS & RESEARCH LIMITED VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
324	W.P.(C) 4295/2016	SURAKSHA PHARMA PVT LTD VS. UOI & ANR
325	W.P.(C) 4297/2016	YASH PHARMA LABORATORIES PRIVATE LIMITED & ANR VS. UNION OF INDIA & ANR
326	W.P.(C) 4298/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
327	W.P.(C) 4299/2016	M/S RAPROSS PHARMACEUTICALS (P) LTD. VS. UNION OF INDIA & ANR

328	W.P.(C) 4300/2016	UNIMARCK PHARMA (INDIA) LTD VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
329	W.P.(C) 4304/2016	WINGS PHARMACEUTICALS PVT LTD & ANR VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
330	W.P.(C) 4305/2016	M/S EAST AFRICAN INDIA OVERSEAS VS. UNION OF INDIA & ANR
331	W.P.(C) 4306/2016	M/S SALUD CARE (I) PVT. LTD VS. UNION OF INDIA & ANR
332	W.P.(C) 4307/2016	MANCARE HEALTH PVT LTD VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
333	W.P.(C) 4348/2016	LIFE CARE FORMULATIONS PVT LTD. VS. UNION OF INDIA & ANR
334	W.P.(C) 4349/2016	UNISON PHARAMACEUTICALS PVT. LTD VS. UNION OF INDIA & ANR
335	W.P.(C) 4350/2016	JENBURKT PHARMACEUTICALS LTD & ANR VS. UNION OF INDIA & ANR
336	W.P.(C) 4351/2016	M/S JUPITER PHARMACEUTICALS LTD VS. UNION OF INDIA & ANR
337	W.P.(C) 4352/2016	MACSUR PHARMAA INDIA PVT LTD VS. UNION OF INDIA & ANR
338	W.P.(C) 4353/2016	M/S NULIFE PHARMACEUTICALS VS. UNION OF INDIA
339	W.P.(C) 4354/2016	UNISON PHARAMACEUTICALS PVT LTD VS. UNION OF INDIA & ANR
340	W.P.(C) 4355/2016	UNISON PHARMACEUTICAL PVT LTD & ANR VS. UNION OF INDIA & ANR
341	W.P.(C) 4356/2016	CHETANBHAI S. SHAH & ORS VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
342	W.P.(C) 4359/2016	STRASSENBURG PHARMACEUTICALS LIMITED VS. UNION OF INDIA & ANR

343	W.P.(C) 4360/2016	TTK HEALTH CARE & ORS VS. UNION OF INDIA & ANR
344	W.P.(C) 4361/2016	M/S SYMBIOTIC DRUGS & DIABETIC CARE PVT. LTD. VS. UNION OF INDIA & ANR
345	W.P.(C) 4362/2016	FOURRTS (INDIA) LABORATORIES PVT. LTD. & ANR VS. UNION OF INDIA & ANR
346	W.P.(C) 4363/2016	MED MANOR ORGANICS PVT. LTD. VS. UNION OF INDIA & ANR
347	W.P.(C) 4478/2016	KUEMEN LABORATORIES PVT. LTD VS. UNION OF INDIA & ANR
348	W.P.(C) 4512/2016	GALPHA LABORATORIES LTD. VS. UNION OF INDIA & ANR
349	W.P.(C) 4526/2016	M/S SALUTE BESTOCHEM & ANR VS. UNION OF INDIA
350	W.P.(C) 4595/2016	SEAGULL LABORATORIES (I) P LTD Vs. UNION OF INDIA & ANR
351	W.P.(C) 4597/2016	CENTAUR PHARMACEUTICALS PVT LIMITED & ORS Vs. UNION OF INDIA & ANR
352	W.P.(C) 4598/2016	SEAGULL LABORATOIRES (I) P LTD. VS. UNION OF INDIA & ANR
353	W.P.(C) 4612/2016	AKUMS DRUGS & PHARMACEUTICALS LIMITED VS. UNION OF INDIA & ANR
354	W.P.(C) 4613/2016	M/S SYSTOPIC LABORATORIES PVT. LTD. & ANR VS. UNION OF INDIA
355	W.P.(C) 4614/2016	SAYORA PHARMA PVT. LTD. VS. UNION OF INDIA & ORS
356	W.P.(C) 4615/2016	M/S SYSTOPIC LABORATORIES PVT. LTD. & ANR VS. UNION OF INDIA
357	W.P.(C) 4617/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
358	W.P.(C) 4618/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR

359	W.P.(C) 4619/2016	M/S FRANKLIN LABORATORIES (I) PVT. LTD. VS. UNION OF INDIA & ANR
360	W.P.(C) 4620/2016	M/S BEEKAY PHARMACEUTICALS VS. UNION OF INDIA & ANR
361	W.P.(C) 4621/2016	M/S PSYCO REMEDIES LTD VS. UNION OF INDIA & ANR
362	W.P.(C) 4622/2016	MASCOT HEALTH SERIES PVT LTD VS. UNION OF INDIA & ANR
363	W.P.(C) 4623/2016	M/S CONSERN PHARMA PVT LTD VS. UNION OF INDIA & ANR
364	W.P.(C) 4624/2016	BIOGENETIC DRUGS PVT LTD VS. UNION OF INDIA & ANR
365	W.P.(C) 4625/2016	MEDIMARK DRUGS & PHARMACEUTICALS VS. UNION OF INDIA & ANR
366	W.P.(C) 4626/2016	SMILAX HEALTHCARE PVT LTD VS. UNION OF INDIA & ANR
367	W.P.(C) 4627/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
368	W.P.(C) 4628/2016	NECTAR BIOPHARMA PRIVATE LIMITED VS. UNION OF INDIA & ANR
369	W.P.(C) 4629/2016	AMWIN PHARMACEUTICALS VS. UNION OF INDIA & ANR
370	W.P.(C) 4642/2016	M/S EDIFICE LABORATORIES VS. UNION OF INDIA & ANR
371	W.P.(C) 4643/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
372	W.P.(C) 4644/2016	M/S MICRO LABS LIMITED VS. UNION OF INDIA & ANR
373	W.P.(C) 4645/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR

374	W.P.(C) 4646/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
375	W.P.(C) 4647/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
376	W.P.(C) 4648/2016	INTAS PHARMACEUTICAL LIMITED & ANR VS. UNION OF INDIA & ANR
377	W.P.(C) 4654/2016	CARE FORMULATION LABS PVT. LTD. VS. UNION OF INDIA & ANR
378	W.P.(C) 4655/2016	M/S FRANCO INDIAN PHARMACEUTICALS PVT.LTD. & ANR VS. UNION OF INDIA & ORS
379	W.P.(C) 4656/2016	M/S MAXTAR BIOGENICS VS. UNION OF INDIA & ANR
380	W.P.(C) 4657/2016	M/S FRANCO INDIAN PHARMACEUTICALS PVT.LTD. & ANR VS. UNION OF INDIA & ORS
381	W.P.(C) 4658/2016	M/S FRANCO INDIAN PHARMACEUTICALS PVT.LTD. & ANR VS. UNION OF INDIA & ORS
382	W.P.(C) 4659/2016	M/S FRANCO INDIAN PHARMACEUTICALS PVT.LTD. VS. UNION OF INDIA & ORS
383	W.P.(C) 4674/2016	M/S FRANCO INDIAN PHARMACEUTICALS PVT.LTD. & ANR VS. UNION OF INDIA & ORS
384	W.P.(C) 4675/2016	M/S FRANCO INDIAN PHARMACEUTICALS PVT.LTD. & ANR VS. UNION OF INDIA & ORS
385	W.P.(C) 4764/2016	TIMON PHARMACEUTICALS PVT LTD VS. UOI & ANR
386	W.P.(C) 4918/2016	M/S ALIVE HEALTHCARE VS. UNION OF INDIA & ANR
387	W.P.(C) 4919/2016	M/S MALIK LIFE SCIENCES PVT. LTD. VS. UNION OF INDIA & ANR
388	W.P.(C) 4920/2016	M/S COMBITIC GLOBAL CAPLET PVT. LTD. VS. UNION OF INDIA & ANR

389	W.P.(C) 4921/2016	ORGANIC LABS PVT LTD VS. UNION OF INDIA & ANR
390	W.P.(C) 4922/2016	MDC PHARMACEUTICALS (P) LTD VS. UNION OF INDIA & ANR
391	W.P.(C) 4923/2016	SINSAN PHARMACEUTICAL PVT. LTD. & ANR VS. UNION OF INDIA & ANR
392	W.P.(C) 4924/2016	M/S ANPHAR ORGANICS PVT LTD VS. UNION OF INDIA
393	W.P.(C) 4926/2016	SINSAN PHARMACEUTICAL PVT. LTD. & ANR VS. UNION OF INDIA & ANR
394	W.P.(C) 4927/2016	M/S PURE & CURE HEALTHCARE PVT. LTD. VS. UNION OF INDIA & ANR
395	W.P.(C) 4963/2016	VARAV BIOGENSIS PVT LTD VS. UNION OF INDIA & ANR
396	W.P.(C) 4964/2016	M/S IOSIS REMEDIES VS. UNION OF INDIA & ANR
397	W.P.(C) 4965/2016	THREE B HEALTHCARE LIMITED VS. UNION OF INDIA & ANR
398	W.P.(C) 4966/2016	GLACIER PHARMACEUTICAL PVT. LTD. & ANR VS. UNION OF INDIA & ANR
399	W.P.(C) 4967/2016	M/S SCOTT-EDIL PHARMACIA LIMITED VS. UNION OF INDIA & ANR
400	W.P.(C) 4968/2016	HORIZONE BIOCEUTICALS PVT LTD VS. UNION OF INDIA & ANR
401	W.P.(C) 4969/2016	ARION HEALTHCARE VS. UNION OF INDIA & ANR
402	W.P.(C) 4971/2016	APPLE FORMULATIONS PVT. LTD. VS. UNION OF INDIA & ANR
403	W.P.(C) 4975/2016	TIMON PHARMACEUTICALS PVT LTD VS. UOI & ANR

404	W.P.(C) 4982/2016	TOSC INTERNATIONAL PVT. LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
405	W.P.(C) 4985/2016	INTAS PHARMACEUTICALS LIMITED & ANR VS. UNION OF INDIA & ANR
406	W.P.(C) 5002/2016	GALPHA LABORATORIES LTD. VS. UNION OF INDIA & ORS.
407	W.P.(C) 5258/2016	SMART LABORATORIES PVT. LTD. VS. UNION OF INDIA & ANR
408	W.P.(C) 5260/2016	M/S APTUS PHARMA PVT. LTD. VS. UNION OF INDIA & ANR
409	W.P.(C) 5264/2016	COOPER PHARMA LTD VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
410	W.P.(C) 5265/2016	M/S SYNCHEM LABORATORIES PVT. LTD. VS. UNION OF INDIA & ANR
411	W.P.(C) 5266/2016	M/S. GS PHARMACEUTICALS PVT LTD. VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
412	W.P.(C) 5267/2016	M/S. GS PHARMACEUTICALS PVT LTD VS. DRUGS CONTROLLER GENERAL OF INDIA & ANR
413	W.P.(C) 5303/2016	M/S KEE PHARMA LIMITED VS. UNION OF INDIA & ANR
414	W.P.(C) 5304/2016	M/S CHEMONIX INDIA PVT LTD VS. UNION OF INDIA & ANR
415	W.P.(C) 5305/2016	SAI TECH MEDICARE PRIVATE LIMITED VS. UNION OF INDIA & ANR
416	W.P.(C) 5306/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
417	W.P.(C) 5307/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
418	W.P.(C) 5308/2016	SAI TECH MEDICARE PRIVATE LIMITED VS. UNION OF INDIA & ANR

419	W.P.(C) 5309/2016	SAI TECH MEDICARE PRIVATE LIMITED VS. UNION OF INDIA & ANR
420	W.P.(C) 5310/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
421	W.P.(C) 5311/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS.\ UNION OF INDIA & ANR
422	W.P.(C) 5312/2016	SAI TECH MEDICARE PRIVATE LIMITED VS. UNION OF INDIA & ANR
423	W.P.(C) 5313/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
424	W.P.(C) 5314/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
425	W.P.(C) 5315/2016	M/S INTACTO VS. UNION OF INDIA & ANR
426	W.P.(C) 5317/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
427	W.P.(C) 5318/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
428	W.P.(C) 5319/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
429	W.P.(C) 5320/2016	SAI TECH MEDICARE PRIVATE LIMITED VS. UNION OF INDIA & ANR
430	W.P.(C) 5321/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
431	W.P.(C) 5322/2016	SAI TECH MEDICARE PRIVATE LIMITED VS. UNION OF INDIA & ANR
432	W.P.(C) 5323/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
433	W.P.(C) 5325/2016	M/S GROUP PHARMACEUTICALS LTD VS. UNION OF INDIA & ANR
434	W.P.(C) 5332/2016	M/S ANPHAR ORGANICS PVT. LTD VS. UNION OF INDIA

435	W.P.(C) 5334/2016	M/S COMBITIC GLOBAL CAPLET PVT. LTD. VS. UNION OF INDIA & ANR
436	W.P.(C) 5338/2016	SUPERMAX LABORATORIES VS. UNION OF INDIA & ANR
437	W.P.(C) 5347/2016	M/S WINDLAS BIOTECH LIMITED & ANR VS. UNION OF INDIA & ANR
438	W.P.(C) 5348/2016	M/S WINDLAS BIOTECH LIMITED ANR VS. UNION OF INDIA & ANR
439	W.P.(C) 5349/2016	M/S WINDLAS BIOTECH LIMITED & ANR VS. UNION OF INDIA & ANR
440	W.P.(C) 5355/2016	M/S. BAL PHARMA LIMITED VS. UNION OF INDIA & ANR.
441	W.P.(C) 5364/2016	GOPISH PHARMA LIMITED VS. UNION OF INDIA & ANR
442	W.P.(C) 5400/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
443	W.P.(C) 5402/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
444	W.P.(C) 5409/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
445	W.P.(C) 5410/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
446	W.P.(C) 5411/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
447	W.P.(C) 5412/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
448	W.P.(C) 5413/2016	SYMBIOSIS PHARMACEUTICAL PRIVATE LIMITED VS. UNION OF INDIA & ANR
449	W.P.(C) 5429/2016	KARNANI PHARMACEUTICALS PVT LTD VS. UNION OF INDIA & ANR

450	W.P.(C) 5484/2016	M/S MERRIL PHARMA PVT LTD VS. UNION OF INDIA & ANR
451	W.P.(C) 5486/2016	WOCKHARDT LIMITED & ORS VS. UNION OF INDIA & ANR
452	W.P.(C) 5495/2016	KLAR SEHEN PVT LTD & ANR VS. UNION OF INDIA & ANR
453	W.P.(C) 5507/2016	M/S AMBIC AAYURCHEM LTD VS. UNION OF INDIA & ANR