IN THE SUPREME COURT OF INDIA
CIVIL WRIT JURISDICTION

WRIT PETITION (CIVIL) NO. _____ OF 2016

IN THE MATTER OF

Dinesh S. Thakur
103 A, Thomas Prabhu Reliance Complex,
First floor, 3-6-278, Opp. Dr. P.Shiva Reddy Eye Hospital
Himayatnagar, Hyderabad Pin 500029
Telangana State **....**Petitioner

Versus

1. **Union of India;**
   Through the Secretary,
   Drugs and Food Quality Control Section,
   Ministry of Health & Family Welfare,
   NirmanBhavan, Maulana Azad Road,
   New Delhi, 110011 ..... Respondent No. 1

2. **The Central Drug Standards Control Organisation, (CDSCO);**
   Through the Drug Controller General of India,
   Kotla Marg, Mandi House,
   New Delhi, 110002. ..... Respondent No. 2

3. **Drugs Consultative Committee,**
   Created under Section 7 of the Drugs & Cosmetics Act, 1940
   Through the Secretary, Ministry of Health & Family Welfare, NirmanBhavan,
   Maulana Azad Road,
   New Delhi 110011 ..... Respondent No. 3

4. **Comptroller & Auditor General of India**
   Pocket-9, Deen Dayal Upadhyay Marg,
   New Delhi-110 124, India ..... Respondent No. 4

A PETITION UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA FILED IN PUBLIC INTEREST

To,
The Hon'ble Chief Justice of India and
His Companion Judges of the
Supreme Court of India

MOST RESPECTFULLY SHOWETH:

1. The present Public Interest Litigation (PIL) petition is filed before this Hon'ble Court under Article 32 of the Constitution of India, on behalf of the patients in India and around the world, seeking this Hon'ble Court's urgent intervention to improve the standards of regulation of the Indian pharmaceutical industry. While there are several problems with the manner in which the pharmaceutical industry is regulated, this petition seeks to raise three specific issues: The first issue pertains to illegal drug approvals, the second issue pertains to changes in India's drug regulatory structure and the third issue pertains to the measures taken to regulate the quality of drugs being made in India for Indians and exported to foreign countries.
2. That with regard to the *first* issue of illegal drug approvals, the 59th report of the Department Related Parliamentary Standing Committee on Health & Family Welfare pointed out how companies like Novartis, UCB Pharma and other un-named companies managed to get existing drugs approved for new indications despite no supporting clinical trials to substantiate the effect of these drugs in curing the new disease indications. For example the 59th Report speaks of Bucilizine, which was earlier approved for allergies and subsequently illegally approved as an appetite stimulant in 2006 despite the fact that there were no authoritative clinical studies to establish the efficacy of the drug in acting as an appetite stimulant. The Hon'ble Standing Committee had

demanded a probe into the approval of Bucilizine and other drugs which were illegally approved. In several cases, the approvals of the drugs highlighted by the Committee were cancelled but the Ministry of Health & Family Welfare (MOHFW) did not carry out any investigation into how the approvals were granted despite the fact that it had provided assurance to the Hon'ble Committee that an investigation would be carried out. In addition, the MOHFW did not take any steps to penalise or recover the illegal profits made by these companies by selling these drugs through illegally granted approvals.

3. The *second* issue raised in this PIL, is the reforms required to India's drug regulatory structure. Subsequent to the 59th Report of the Parliamentary Standing Committee, the Central Government had setup an expert committee called the Katoch Committee Report which had recommended a series of measures to reform the manner in which the CDSCO functioned. A true and correct copy of the Report of the Expert Committee headed by Dr. V.M. Katoch dated 20.11.2012 is annexed herewith and marked as **ANNEXURE P-1** (Pgs. __ to ___). Although the Central Government had informed the Parliamentary Standing Committee that it would act on those reforms, it has not carried out any substantial reform till date.
4. The *third* issue raised in this PIL is the poor regulation of 'Made in India' drugs as a result of which several of these drugs regularly fail testing in both India and foreign countries. A pharmaceutical drug which fails quality tests can be classified as either 'counterfeit' or 'sub-standard'.

The phrase counterfeit, which is referred to as “spurious” under the Drugs & Cosmetics Act, usually refers to cases where an element of fraud is involved since the drugs manufactured by illegal operators are falsely marketed as a product of an established company and usually contain little or no active ingredient. The latter phrase, ‘sub-standard’ (or ‘Not of Standard Quality’, NSQ), refers to drugs which although manufactured by a licensed pharmaceutical manufacturer, are not compliant with quality standards prescribed in the Indian Pharmacopeia because of poor manufacturing processes and poor quality control standards. Contrary to common perception, in India, the problem of ‘sub-standard’ or NSQ drugs is far more widely prevalent than ‘counterfeit’ or ‘spurious drugs’. This is apparent from the Government of India’s own surveys. For example, in the last CDSCO survey in the Indian market, conducted in 2009, the percentage of spurious drugs detected in the Indian market has wavered between 0.3% in 2003-04 to 0.17% in 2007-08. The percentage of NSQ drugs has however been as high as 7.5% in 2004-05 before falling to 6.3% in 2007-08. Even these figures are likely inaccurate because of the design of the survey. Other government documents like the CAG Audit Report no. 18 of 2008-09 on procurements by the Armed Forces Medical Stores (AMFS), notes that the rate of rejection for locally procured medicine, due to samples failing quality tests,

increased from 15% to 31% during 2006-07 to 2010-11. The average rate of rejection during the three year period of 2008-09 to 2010-11 was therefore 24% approximately. Similarly, a study conducted in Ghana, determined that a large percentage (82.73%) of a particular drug (Ergometrine) that was imported primarily from India was sub-standard. (Post-Market Quality Surveillance Project: Maternal Healthcare Products on the Ghanaian Market; February, 2013). In 2013, Vietnam reported similar problems with 'Made in India' medicine and placed import bans on 45 Indian pharmaceutical companies.

5. Such a wide prevalence of sub-standard (or NSQ) drugs in the Indian market and Indian exports is a matter of grave concern because the medical community has repeatedly warned about the adverse impact of sub-standard drugs. For example, a study published in the prestigious *British Journal of Clinical Pharmacology* [Johnston & Holt, 'Substandard drugs: A potential crisis for public health', 78(2) (2013) at p. 218-243]. The study makes the following important points:

    - "Although falsified drugs have perhaps received most of the attention with respect to causing unnecessary deaths, substandard drug manufacture also leads to morbidity and mortality";
    - "The inadvertent use of suboptimal doses of drugs is likely to be one of the key factors contributing to

antimicrobial resistance and thereby leading to the wider spread of disease".

In a different study published in *Trends in Pharmacological Sciences* [Newton et. al. 'Impact of poor-quality medicines in the developing world', 31(3-3) (2010) at p.99-101] the authors list the following as the consequences of sale of poor-quality medicine:

- Increased mortality and morbidity;
- Engendering of drug resistance and loss of medicine efficacy;
- Loss of confidence in health systems and health workers;
- Economic loss for patients, their families, health systems, and the producers and traders in good quality medicines;
- Adverse effects from incorrect active ingredients;
- Waste of enormous human effort and financial outlay in development of medicines, optimising dosage, carrying out clinical trials, discussing policy change, and manufacturing medicines;

6. From the above studies it is rather clear that sub-standard drugs present a clear and present danger to public health. India will therefore need to take urgent measures to ensure fewer NSQ drugs are consumed by Indian citizens. The Petitioner conducted an extensive study of the prevailing regulatory framework in India by filing more than a hundred

applications under the Right to Information Act (RTI) across the country with different regulatory authorities and also by studying previous reports on drug regulation by expert committees. From this extensive research conducted by the petitioner, he has been able to broadly identify the most problematic issues with drug regulation in India. Based on this research, the Petitioner has filed the present PIL.

7. It is humbly submitted that this Hon'ble Court has made several important interventions in issues involving the health of the citizens of this country. In this regard, it may be pertinent to mention that this Hon'ble Court was pleased to admit a PIL on the issue of quality of medicine as far back as 1987, in the case of *Vincent Panikurlangara*v. *Union of India* AIR 1987 990. In this case, this Hon'ble Court, called on the Central Government to strengthen the process of drug regulation and ensure strict enforcement of the law on the ground in order to ensure that the quality of drugs is maintained.Unfortunately, little has changed since these directions by this Hon'ble Court. Since the *Vincent Panikurlangara* judgment in 1987, this Hon'ble Court has been pleased to pass judgments in several PILs under Article 32 of the Constitution of India to protect public health in the country. These judgments have included directions for better regulation of blood banks (*Common Cause* v. *Union of India* AIR 1996 SC 929), for better equipment and care to be provided by all primary health centres and government

hospitals (*Paschim Banga Khet Mazdoor Samity and others* v. *State of West Bengal and another*(1996) 4 SCC 37)and for the protection of the health of workers in the asbestos industry (*Consumer Education and Research Centre and others* v. *Union of India and others* AIR 1995 SC 922). Since the year 2000, the Hon'ble Supreme Court has stepped in to ensure the safe regulation of genetically modified crops and food (*Aruna Rodrigues* v. *Union of India* W.P. no. 260 of 2005; *Gene Campaign* v. *Union of India* W.P. no. 606 of 2007) and for better regulation of clinical trials (*Swasthya Adhikar Manch and Anr. v. Union of India* W.P. No. 33 & 79 of 2012. More recently the Supreme Court has admitted a PIL against the Central and various state governments (*Swami Achyutanand Tirth & Ors.* v. *Union of India &Ors.* W.P.No.159 of 2012) regarding the state of implementation of the Food Safety and Standards Act, 2006 across the country.

A. THE PETITIONER'S CREDENTIALS

8. It is humbly submitted to this Hon'ble Court that the petitioner is an Overseas Citizen of India (OCI), who spends considerable time in India and has immediate family who reside here. . The petitioner is a public health activist, who after almost 20 years of experience working in a number of different positions in both the Indian and American pharmaceutical industry, turned a whistle-blower, at great personal risk, against his former employer Ranbaxy

Laboratories Ltd. (“Ranbaxy”) who were involved in widespread data falsification in order to secure marketing approvals for its products. The petitioner had secured access to this information regarding falsification of the data while working as the Director & Head of the Research Information and Portfolio Management at Ranbaxy betweenJune 2003 and April 2005. Although the petitioner had made repeated attempts to convince the senior management at the company to take corrective action, his attempts went un-heeded. Instead his position was compromised by the company thereby making it difficult to continue his employment. He resigned from his role and worked with the US Food & Drug Administration as a confidential informant between 2005 and 2007. In April of 2007, he filed a lawsuit against Ranbaxy in the United States of America (“US”) under the Federal False Claims Act and similar state laws on the grounds that Ranbaxy was supplying substandard medicine to government agencies in the US. (*United States ex rel. Dinesh S. Thakur v. Ranbaxy USA Inc., et. al.,* Civil Action No. 1:07-00962-JFM (D. Md.) The United States government simultaneously initiated civil & criminal proceedings against Ranbaxy on the basis of information submitted by the petitioner. (*United States of America* v. *Ranbaxy Laboratories Ltd. et.al.* Civil Action No. 12-250 (D. Md.)

9. In May 2013, after a long legal battle, Ranbaxy pleaded guilty to seven counts of criminal felony charges and agreed to pay $500 million in penalties & fines to the United States government in order to resolve the various criminal and civil claims in the US District Court of Maryland. Under the provisions of the False Claims Act, the petitioner was awarded a sum $48 million dollars for risking his career and his life in order to expose the wrongdoings at Ranbaxy, for saving public funds and most importantly for saving the lives of millions of patients who consume substandard medication manufactured by Ranbaxy. After news of Ranbaxy's settlement broke in India, several people in the Indian medical community had raised concerns because all of Ranbaxy's manufacturing facilities that were indicted were located in India and were supplying medicine to Indian citizens. Eventually the matter reached Parliament, when Hon'ble MPs raised questions during 'Question Hour'. The then Minister of Health Ghulam Nabi Azad on August 6, 2013 had informed the Rajya Sabha that the DCGI had already been ordered to review the GMP Compliance of the manufacturing facilities of Ranbaxy. A true and correct copy of the Order passed by the Government of India directing investigation into Ranbaxy Scandal dated 11.06.2013 is annexed herewith and marked as **ANNEXURE P-2** (Pgs. __ to ___)

10. In recognition of the petitioner's role in uncovering this criminal behaviour, he has given recognized through awards and honours including the Joe. A. Callaway Award for Civic Courage, the Association of Certified Fraud Examiners (ACFE's) Cliff Robertson Sentinel Award, Taxpayer Against Fraud (TAF's) Whistle blower of the Year. From the settlement amount received, the petitioner has contributed generously to various charities in India and abroad, including the supporting Gyanshala, a charitable school for

children in UP and Bihar, and Cankids, a charitable institution for care of children with cancer. The petitioner also contributes to educational causes by funding fellowships in his *alma matter*, the University of New Hampshire for research in bioengineering and in healthcare analytics. He also offers professional services through his company Medassure Global Compliance Corporation for improving the quality of medicine to the pharmaceutical industry.

11. Over the last two years, the petitioner has dedicated a substantial amount of his time and resources towards improving the quality of regulation of the pharmaceutical industry in India by conducting research, giving talks, writing academically and for newspapers to increase awareness for the issue of pharmaceutical regulation in India. During this period of time, the petitioner has discovered substantial shortcomings in the manner in which the pharmaceutical industry is regulated in India, including in some cases the non-application and misinterpretation of the Drugs & Cosmetics Act, 1940 by statutory authorities who are responsible for implementation of the legislation. In order to better understand these issues, the petitioner through his advocates filed over 120 applications under the Right to Information Act, 2005 with various state and central authorities to access hitherto inaccessible information on the manner in which drug regulation is implemented in India. The deficiencies, discovered by the petitioner during the course of his research, can have a substantial bearing on the quality of medicine consumed by not only Indians but also citizens in countries which import medicines from India. Such substandard medicine can have a very serious adverse effect on public health, since not only do they fail to

cure the ailments as intended but in several cases can cause increased resistance to infectious diseases thereby endangering public health.

12. Given the severe risk posed to public health in India due to the extremely poor quality of regulation of the Indian pharmaceutical industry, the petitioner has felt compelled to move this Hon'ble Court in public interest, through the present PIL.

B. ABOUT THE RESPONDENTS

13. Before explaining the reasons for impleading the various respondents in this case, it is first necessary to highlight the regulatory architecture created by the Drugs & Cosmetics Act, 1940 ("D&C Act"). For the last seventy years, the D&C Act has created a system whereby drug regulation has been split between the Centre and States/Union Territories (U.Ts). While the central regulator, which is the Drug Controller General of India (DCGI) is the only authority which can regulate the marketing of new drugs within the territory of India, it is only the state/U.T regulators (often referred to as "state licensing authorities") which can issue licences to a pharmaceutical company to manufacture a drug which has already received marketing permission from the DCGI. To illustrate with the help of an example, if a new Drug X which cures hepatitis is to be manufactured and sold in India, the manufacturer will first have to approach the DCGI for marketing approval. This permission can be

granted only after the DCGI verifies all of the clinical information proving therapeutic efficacy of the drug as submitted by the manufacturer. The marketing approval received from the DCGI will suffice for the manufacturer to sell the drug throughout the territory of India. After permission is given by DCGI, if the drug is to be manufactured within India, the State Licensing Authority (SLA) is left with the task of issuing a licence to manufacture the drug within its jurisdiction. This licensing power is delegated to the SLAs by the Central Government under the D&C Rules, 1945. Therefore once a manufacturing licence is issued by one state, the drug manufactured under that licence can be sold anywhere in the country through interstate commerce. Once a ‘new drug’ has been in the market for a period of 4 years, it loses its ‘new drug’ status. After this 4 year period, any pharmaceutical company seeking to manufacture the drug can approach the SLA directly without a marketing approval from the central regulator.

14. The task of testing drugs being sold in the market to ensure adequate quality is conducted by Drug Inspectors from both the Central Government and the State Governments. Samples are randomly drawn from the market by Drug Inspectors and then sent to either central or state laboratories where the drugs are tested by Government Analysts as per protocols laid down in the Indian

Pharmacopeia, which is a publication prepared by the Indian Pharmacopeia Commission (IPC) – an expert body. If the drug is found to be NSQ or spurious or adulterated or misbranded, the Government analyst makes a note of the same in the test report and sends the report back to the Drug Inspector. The Drug Inspector of either the State or Central Government may then institute criminal proceedings against the manufacturer under the Drugs & Cosmetics Act, 1940. Simultaneously, the licensing authority may impose certain administrative measures such as suspension or cancellation of licences. If the manufacturing licence has been issued by a SLA from a different state, the Drug Inspector will, in most cases transmit a copy of the report to the SLA which issued the license requesting it to take action. After an investigation, the SLA may cancel or suspend a manufacturing licence.

15. Due to the requirement of a separate licensing authority in each state, there are a total of 36 state/UT SLAs/regulators plus 1 central regulator, leading to a total of 37 regulators who are responsible for the regulation of drugs in India. To the best of the knowledge of the petitioner, these SLAs function as a part of their respective state governments and each state government can have a different administrative structure for their respective SLAs. Recruitment rules, qualification criteria and the level of training imparted often differ amongst these different state regulators. (However the

qualification criteria for Drug Inspectors and Government Analysts is prescribed in the Drugs & Cosmetics Rules, 1945) For example, the Director of the Drug Control Administration, Andhra Pradesh is usually an officer from the Indian Police Service (IPS) while most other states promote Drug Inspectors with degrees in Pharmacology to the position of State Drugs Controller. Since these regulators function solely under the purview of the State Governments, the DCGI cannot exercise administrative or financial control over the SLAs. As a result there is considerable inconsistency in the manner in which each state regulator/SLA operates and this inconsistency in application of law across different states is one of the main reasons for the poor quality of regulation in India.

16. **Respondent No. 1 – The Ministry of Health and Family Welfare (Drug & Food Quality Control – DFQC Section):** It is humbly submitted to this Hon'ble Court that the Ministry of Health & Family Welfare (MOHFW) is the Ministry of the Central Government which is responsible for drafting policy and legislation for regulating the quality of medicine that is manufactured and marketed in India. The MOHFW is also the 'parent' Ministry of Respondent No. 2, which is the Central Drug Standard Control Organisation (CDSCO) and exercises direct control over the functioning of the CDSCO. The MOHFW is a necessary party since the petitioner is

seeking certain remedies qua the CDSCO, which virtually functions as an arm of the MOHFW.

17. **Respondent No. 2 – The Central Drugs Standard Control Organisation (CDSCO):** It is humbly submitted to this Hon'ble Court that most of the remedies in this petition are being sought *qua* the CDSCO, which is the main agency at the Centre responsible for discharging the functions of the Central Government under the D&C Act. It is headed by the Drug Controller General of India (DCGI). Despite the best efforts of the petitioner, he has been unable to identify the law or executive order under which the CDSCO came into existence. As a last resort, the petitioner through his advocate filed applications under the RTI Act with the CDSCO and the Ministry of Health and Family Welfare (MOHFW) requesting a copy of the law/executive order under which the CDSCO was created. Both these public authorities however provided only vague answers. For example, the Public Information Officer (PIO) of the CDSCO in his reply stated "The CDSCO is the name given to the office of DCG(I) appointed under rule 21(b) by the Central Government and the other offices under his control." The PIO of the MOHFW in his reply stated "it is informed that the Central Drug Standard Control Organisation (CDSCO) headed by the Drug Controller (India) flows from the various provisions of the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945." Neither reply provides a

satisfactory answer regarding the law under which the CDSCO was created.

18. **Respondent No. 3 – The Drugs Consultative Committee:** It is humbly submitted to this Hon'ble Court that the Drugs Consultative Committee (DCC) is a statutory authority created under Section 7 of the D&C Act, 1940. The DCC consists of representatives from all the State Governments and 2 representatives of the Central Government. Its main function as described in Section 7 is to "secure uniformity throughout India in the administration of this Act". The DCC is a necessary party since the Petitioner has challenged certain guidelines issued by the DCC and has also requested the Hon'ble court to issue certain directions to the DCC to ensure better inter-state co-operation in administration of the D&C Act.

C. RECOMMENDATIONS MADE BY THE 59TH REPORT OF THE DEPARTMENT RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH & FAMILY WELFARE AND THE MOHFW APPOINTED EXPERT COMMITTEE HEADED BY DR. KATOCH

19. It is humbly submitted to this Hon'ble Court that in 2012, the Department Related Parliamentary Standing Committee on Health & Family Welfare, which is a Parliamentary institution, conducted a detailed investigation into the functioning of the Central Drug Standard Control Organisation (CDSCO). It tabled its findings on the floor of Parliament in its 59th report on May 8, 2012. Since this report had raised serious issues with the functioning of the

CDSCO, the MOHFW setup an Expert Committee under Dr. V.M. Katoch, Director-General of Indian Council of Medical Research (ICMR) to study the Standing Committee's report and submit recommendations to the Government. While waiting for the Report of the Katoch committee, the MOHFW submitted an interim "Action Taken Report" (ATR) to the Government on September 12, 2012, followed by a final "Action Taken Report" dated December 28, 2012, on the basis of recommendations made by the Expert Committee headed by Dr. Katoch which had submitted its report on November 20, 2012. On the basis of this final ATR, the Standing Committee prepared its 66th Report, titled "Action Taken by the Government on the Recommendations/Observations contained in the Fifty-Ninth Report on the Functioning of Central Drugs Standards Control Organisation (CDSCO)." This report was tabled on the floor of Parliament on 26th April, 2013.

20. It is humbly submitted to this Hon'ble Court that most of these recommendations made by the Parliamentary Standing Committee and the Expert Committee have not yet been implemented despite the MOHFW accepting most recommendations of these Committee. The most important issues raised by these reports are discussed below in greater detail.

I. The need to create an efficient system for 'Nation-wide Drug Alert & Recall System'

21. It is humbly submitted to this Hon'ble Court that one of the most important functions of any drug regulatory mechanism is to quickly detect the entry into the market of drugs that may be not of standard quality (NSQ), spurious, adulterated or misbranded and ensure that the same are speedily recalled. Recalls of NSQ drugs can be either voluntary or mandatory. Voluntary recalls are done by the manufacturer when it detects certain defects in batches which have already been released in the market. As a part of Good Manufacturing Practices (GMP) included in Schedule M to the Drugs & Cosmetics Rules, 1945, each manufacturer is required to have a system in place to withdraw drugs from the market. However unlike in the developed world where manufacturer regularly recall their own products from the market due to a fear of prosecution, in India it is unheard of for manufacturers to voluntarily recall their own drugs. On the other hand, a mandatory recall is when a drug regulator mandatorily orders the manufacturer to withdraw entire batches from the market due to manufacturing defects. Such mandatory recalls are based on information received either from a government laboratory or the market. Such a system would require a country to have a system of laboratories in place to draw samples from the market on a random basis, test the same and issue alerts to healthcare practitioners and mandate recalls once a drug is detected to be NSQ, spurious, adulterated or misbranded. Prosecutions

and convictions are secondary to this objective of recalls. The immediate concern from a public health perspective is to ensure the withdrawal of the entire batch from the market so as to prevent patients from consuming such drugs in the future. This can be done by first issuing a nationwide alert, with the batch number and name of the manufacturer, once a NSQ drug is detected in the market. The drug alert is then required to be followed by an order from the regulator to the manufacturer to recall the batch of the not-standard quality drug. Once the regulatory system has confirmed the drug alert and recall, it can proceed to investigate and prosecute for offences committed under the D&C Act. In a country like India, where there are 37 different regulators, despite there being one common market, it is absolutely essential that any system of drug alerts and recall be centralised for the entire nation, failing which drugs recalled from only one state will be sold in another state.

22. Surprisingly, even 75 years after the enactment of the Drugs & Cosmetics Act, 1940 India as a country lacks an effective law mandating regulators to issue nationwide safety alerts and drug recalls. In its 59th Report, the Department Related Parliamentary Standing Committee expressed its shock at the lack of an effective system of drug alerts and recall in the country.

23. In the Interim Action Taken Report in response to the 59th report, the MOHFW while providing para-wise replies to the

59th Report had declined from committing to the creation of a nationwide recall mechanism on the grounds that it was the duty of the states to create such a mechanism. It did however say that the CDSCO may create a drug alert system. The failure to commit to the creation of a 'Drug Recall' system by the MOHFW to the Parliamentary Standing Committee is most surprising when seen in the context of media reports in November, 2012 that the CDSCO had actually published **draft** *Guidelines on Recall and Rapid Alert System for Drugs* on October 22, 2012 proposing a nation-wide recall system. In a news report published in *Express Pharma* on November 22, 2012 titled *CDSCO drafts guidelines on recall and rapid alert system for drugs* the DCGI was quoted as saying the following: *We have published draft guidelines on October 22, 2012 and asked the stakeholders to revert back before November 7, 2012. Once we will get responses, we will review them accordingly. The suggestions or objections, if found to be in public interest will be forwarded to the Ministry of Health. The review process will take 45 days and then will be sent to the Health Ministry and then to the Law Ministry. Overall, we are expecting that it will take three to four months to become an act.*

24. After reviewing the news reports mentioned above, the petitioner conducted further research by reviewing the following reports: the report of the Expert Committee

headed by Dr. V.M. Katoch and the Final ATR submitted to the Standing Committee by the MOHFW. These reports were finalised and submitted to the Hon'ble Standing Committee in November, 2012 but both reports fail to mention to the Standing Committee that the CDSCO had in fact published draft guidelines for national recalls. The petitioner is unable to explain as to why the MOHFW failed to inform the Standing Committee that the CDSCO had in fact already issued published draft guidelines on drug recalls.

25. Thereafter, these Guidelines were discussed at the 45th meeting of the Drugs Consultative Committee (DCC) held on February 4 and 5, 2013 at New Delhi. The report of the DCC meeting clearly states that the Guidelines on Recall and Rapid Alert System for Dugs (Including Biologicals & Vaccines) was available on the website of the CDSCO and requested all State Drug Control Authorities to comment on the same before the Guidelines were notified into the law. Thereafter these Guidelines were once again discussed at the 46th meeting of the DCC held on November 12 and 13, 2013 at New Delhi. A true and correct copy of the Report of the 46th meeting of the Drugs Consultative Committee dated 12 & 13 November, 2013 is annexed herewith and marked as **ANNEXURE P-3** (Pgs. __ to ___). The report of the DCC meeting notes that several comments were received in response to the draft guidelines and that the DCC "may kindly consider and suggest the methodology for finalizing and approving the guidelines for the purpose of implementation." Since none of the subsequent DCC reports discussed the

implementation of the aforementioned Guidelines, the petitioner decided to file applications under the RTI Act in order to determine whether the CDSCO and State Governments were implementing these guidelines. The petitioner through his advocate filed two sets of RTI Applications with Respondent No. 2 (the CDSCO) on April 15, 2015 and May 22, 2015 asking the authority whether it had any mechanism or guidelines to effect a drug recall. The responses omitted to mention the draft guidelines referred to above and were also silent on the existence of any effective nationwide system for drug recalls. Instead, in its reply, the CDSCO placed the responsibility of recalling NSQ drugs squarely at the doorstep of State authorities.

26. The petitioner then filed applications under the RTI Act with State Licensing Authorities of Andhra Pradesh, Tamil Nadu, Karnataka, Maharashtra, Himachal Pradesh and Uttarakhand. The relevant questions asked in the RTI Applications to all these states was whether they followed any guidelines or rules to recall drugs that were detected as being 'Not of Standard Quality'.

27. The replies provided by each one of these states is tabulated below:

State Name	**Response provided to Query No. 1 on Drug Recall**
Andhra Pradesh	The State PIO provided the applicant with a copy of Circular No. 24/DG/Drugs/2013 laying out the procedure for recalling NSQ drugs in the state of AP – there was no mention in the reply of the CDSCO's draft guidelines.
Himachal Pradesh	After a successful appeal against the PIO's initial reply, the PIO provided a copy of the

	"Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008". As per information available to the petitioner, these guidelines were recommended at the 40th meeting of the Drugs Consultative Committee (DCC) held on 29.6.2009 and have been available on the website of the CDSCO for several years but these guidelines do not deal with recall procedures. These guidelines only deal with prosecutions – there was no mention, in the reply, of the CDSCO's draft guidelines.
Karnataka	The State PIO provided a copy of the "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008". As per information available to the petitioner, these guidelines were recommended at the 40th meeting of the Drugs Consultative Committee (DCC) held on 29.6.2009 and have been available on the website of the CDSCO for several years but these guidelines do not deal with recall procedures. These guidelines only deal with prosecutions – there was no mention, in the reply, of the CDSCO's draft guidelines.
Tamil Nadu	The State PIO in response merely stated "Schedule M Para 27 of the Drugs & Cosmetics Rules, 1945". It should be noted that Para 27 of Schedule M only provides the "Standard Operating Procedure" (SOP) to be followed by the manufacturers when a recall is conducted. Schedule M does not however deal with recall procedures required to be followed by the SLAs – there was no mention, in the reply, of the CDSCO's draft guidelines on drug recalls.
Uttarakhand	The State PIO provided the following answer "Drug Licensing Authority/Drug Controller

	orders for recall of drug which are reported to be not of standard quality by report of Government Analyst and/or which comes to his knowledge and which he has reasons to believe is not of standard quality in exercise of Rules 74(f), 76(h)(i) of the Drugs & Cosmetics Rules, 1945 framed under the Drugs and Cosmetics Act, 1940." It is humbly submitted that neither of the Rules cited by the authority deal with recall procedures – there was no mention, in the reply, of the CDSCO's draft guidelines.
Maharashtra	The State PIO merely states that "The Food & Drug Administration, M.S. recall Not of Standard Quality drugs as per provision laid down in the Drugs & Cosmetics Rules, 1945". There is no specific provision in the D&C Rules dealing with national recall – there was no mention, in the reply, of the CDSCO's draft guidelines on drug recall.

28. As can be seen from the above table, not a single one of the 6 states above is aware of the **draft** "Guidelines on Recall and Rapid Alert System for Drugs" published by the CDSCO on its website on October 22, 2012 and circulated in the 45th DCC meeting which is attended by all State Controllers. More worryingly, it appears that all of the above states, with the exception of Andhra Pradesh (AP), do not have any specific rules or regulations governing the manner in which NSQ drugs are to be recalled from the market. It is therefore entirely possible that most Indian states have not being

conducting recalls. In a recent interview to the press, (Amend D&C Act to make manufacturers accountable for prompt recalling of NSQ drugs from market: Kerala deputy DC, *Pharmabiz* October 12, 2015) the Deputy Drug Controller of Kerala made a public appeal for an amendment to the D&C Act to make manufacturers accountable for promptly recalling NSQ drugs from the market.

II. Illegal drug approvals granted by CDSCO & the failure of MOHFW to investigate the approvals

29. It is humbly submitted to this Hon'ble Court that the Parliamentary Standing Committee in its 59th Report had discovered shocking criminal acts at the CDSCO including illegal approvals granted for marketing of drugs on the basis of forged opinions. Despite the MOHFW assuring the Committee that investigations would be ordered into the illegal approvals, no action has been taken three years hence. The specific details of these illegalities are discussed in greater details below.

30. Illegal approval of Aceclofenac with Drotaverine: In the case of approval of a fixed dose combination of Aceclofenac with Drotaverine the committee noted in its 59th Report that the combination was not approved in any developed country in the world and that the CDSCO had basically allowed the manufacturer to choose its own experts rather than nominate independent experts to give an opinion on the safety and efficacy of the combination. Since several of the

expert opinions were identical to each other, it raised the Committee's suspicion that the doctors had simply signed the opinions prepared by the manufacturer instead of preparing their own individual opinions. The Standing Committee thus demanded an investigation into the process by which CDSCO approved this drug combination.

31. In its Final ATR, the MOHFW has noted that the Expert Committee headed by Dr. V.M. Katoch had recommended instituting an enquiry into the matter and that "As recommended by the Hon'ble Committee, the DCG(I) will constitute an enquiry committee to investigate into the matter". In response to this submission by the MOHFW, the Hon'ble Standing Committee in its 66th report, made the following scathing observations: "*The Committee is aghast to note the paralytic inertia gripping the Ministry which is preventing it from taking action against guilty official(s) of CDSCO and others involved in proven cases of delinquency and illegality six months should have been more than enough to not only inquire into the misdeeds of those who had so wantonly indulged in the above cited gross irregularity but also sufficed to take exemplary action against them so as to deter others.*

32. The petitioner through his advocate filed an application under the RTI Act, 2005 to seek a copy of the order from the MOHFW to the DCGI to conduct an enquiry into this matter and also for a photocopy of the final investigation report.

The MOHFW replied to the petitioner's advocate on September 17, 2015 informing him that "no separate orders in this regard have been issued by the MOHFW".

33. Illegal Approval of Buclizine:Similarly the Hon'ble Standing Committee in its 59th Report had noted that **Buclizine**, a drug manufactured by UCB, a Belgian company had been approved by the CDSCO as an appetite stimulant despite the fact that this drug was not approved in its home country, Belgium for appetite stimulation. The Hon'ble Committee also noted that the company's own data indicated that no clinical studies had been conducted to determine whether the drug worked adequately as an appetite stimulant. In fact many countries such as Brazil, Bolivia, Luxemburg, Malayasia, South Korea had even discontinued use of Buclizine. The Hon'ble Committee was of the opinion that the drug had been approved illegally in India and had demanded an investigation into the approval.

34. In its Final ATR, the MOHFW has noted that the Expert Committee headed by Dr. V.M. Katoch had recommended instituting an enquiry into the approval of Buclizine and that "As recommended by the Hon'ble Committee, the DCG(I) will constitute an enquiry committee to investigate into the matter". The Hon'ble Standing Committee, in its 66th Report responded by noting its extreme displeasure that the MOHFW had not yet taken any remedial action and once again called for an investigation into the matter.

35. The petitioner through his advocate filed an application under the RTI Act, 2005 to seek a copy of the order from the MOHFW to the DCGI to conduct an enquiry into the approval of Bucilizine and also for a photocopy of the final investigation report. The MOHFW replied to the petitioner's advocate on September 17, 2015 informing him that "no separate orders in this regard have been issued by the MOHFW".

36. Illegal Approval of Letrozole: In line with the two cases discussed above, the Hon'ble Standing Committee in its 59th report discovered that the CDSCO had granted approval to Novartis to market its anti-cancer drug Letrozole as a drug to boost fertility despite the fact that there was data to demonstrate that Letrozole could cause birth defects. This drug was subsequently banned in India, 4 years after its approval but as pointed out by the Hon'ble Committee, the government never fixed any responsibility on the persons who granted such a blatantly illegal approval.

37. In its Final ATR, the MOHFW has noted that the Expert Committee headed by Dr. V.M. Katoch had recommended instituting an enquiry into the approval of Letrozole and that "As recommended by the Hon'ble Committee, the DCG(I) will constitute an enquiry committee to investigate into the matter". The Hon'ble Standing Committee, in its 66th Report responded by noting its extreme displeasure that the MOHFW had not yet taken any remedial action. It stated the

following: *The Committee find it deeply perturbing as to why the Ministry has failed to take action in this very open and shut case of impropriety and criminal lapse though more than six months have elapsed the Committee strongly feel that if perpetrators of such illegalities and collusive acts which are detrimental to public health are allowed to go scot-free then the total collapse of an ethical health care system is inevitable.*

38. The petitioner through his advocate filed an application under the RTI Act, 2005 to seek a copy of the order from the MOHFW to the DCGI to conduct an enquiry into the approval of Letrozole and also for a photocopy of the final investigation report. The MOHFW replied to the petitioner's advocate on September 17, 2015 informing him that "no separate orders in this regard have been issued by the MOHFW".

39. Illegal approval of Deanxit (Flupenthixol&Melitracen)**:** As with the cases above, the Hon'ble Standing Committee in its 59th Report had alleged that the CDSCO had committee major violations in law when it approved Deanxit which is a combination of Flupenthixol&Melitracen. As pointed out by the Hon'ble Committee Deanxit is banned in its country of origin (Denmark). Further Melitracen which is one of the two drugs in the combination was never approved for use in India which means that it cannot be sold in India. The drug was marketed in India for depression and its marketing

approval was suspended only after a review was forced by the 59th Report of the Standing Committee.

40. In its Final ATR, the MOHFW had not mentioned that it would order an investigation into the approval of Deanxit. Instead it had mentioned that the manufacturer of the drug shall be instructed to establish the safety and efficacy of the FDC within 6 months failing which the drug would be considered for being prohibited for manufacture and marketing in the country. In its 66th Report, the Hon'ble Standing Committee noted its extreme displeasure with the Ministry's stand stating that "*3.110 If any drug is promoted for unapproved indications, DCGI has the statutory duty to take action and even cancel marketing approval. The Committee is aghast that no action was taken against the Danish manufacturer, Lundbeck even when it was openly flouting Indian laws. Compare the lack of action in India with the United States where for a similar offence Pfizer had to shell out Rs. 2,300 crores for promoting gabapentin for unapproved indication.*"

41. The petitioner through his advocate had filed an application under the RTI Act with the MOHFW requesting whether an enquiry had been ordered into the approval of Deanxit as had been promised to the Standing Committee by the MOHFW. This was an erroneous question as the MOHFW had actually not made any such submission. Nevertheless in the response the MOHFW did state although it had

apprised the Standing Committee that an investigation would be ordered into the approval of Deanxit no separate order in this regard had been issued by the MOHFW.

42. Illegal approval of placenta for new indications: As with the cases above, the Hon'ble Standing Committee had noted in its 59th Report that 'placenta' had been illegally approved for additional indication in a clear violation of the rules. Additionally, the Hon'ble Committee noted that the CDSCO has granted approval in a record 4 days of receiving the permission request from the manufacturer. The Hon'ble Committee had recommended an enquiry into the said letter. In pertinent part the Hon'ble Committee stated "*The Committee recommends an enquiry into the said letter. The responsibility should be fixed and appropriate action taken against the guilty. The Committee should be kept informed on this case."* In the final ATR, the MOHFW had noted that informed the Hon'ble Committee that the matter was referred to the Expert Committee which had recommended instituting an enquiry into the matter and that the MOHFW would order the DCGI to institute an enquiry into the same. In its 66th report, the Hon'ble Committee had expressed its extreme displeasure with the Ministry and demanded immediate action be taken against the bureaucrats who granted the illegal approval in this case.

43. Notwithstanding these strong comments by the Hon'ble Standing Committee, the MOHFW is yet to take any action

against the CDSCO. The petitioner through his advocate confirmed this fact by filing an application under the RTI Act on June 9, 2015 requesting the MOHFW for details on follow up action taken after the 59th Report. In a reply dated September 16, 2015 the Appellate Authority at the MOHFW merely provided photocopies of the final ATR submitted by the MOHFW. This indicates that the MOHFW has not ordered the said enquiry..

44. Illegal approval of nimensulide for children: As with the cases above, the Hon'ble Standing Committee in its 59th report that the CDSCO had approved nimensulide for even children (0-12 years) without conducting clinical trials in India. After the drug was banned in Europe seven years ago because of its dangerous effects on children, the Indian media covered the controversy after which the drug was finally banned for children only 4 years ago. Using very strong language the Hon'ble Committee stated the following, while making a demand for an investigation into the approvals:*7.51 The Committee takes special notice of this case of persistent insolence on the part of CDSCO and hopes that never again shall the DCGI approve drugs in violation of laws, that too for use in neonates and young children.*

45. Thereafter the MOHFW in its final ATR had noted that the Expert Committee under Prof. V.M. Katoch had recommended an enquiry into the approval and that the

MOHFW would order the DCGI to carry out such an inquiry. The petitioner through his advocate filed an application under the RTI Act on June 9, 2015 seeking details of the follow-up action taken by the MOHFW. In response the Appellate Authority on September 16, 2015 stated that the "information sought is not available in the Action Taken Report/relevant file".

III. Failure by CDSCO to investigate the disappearance of files for controversial drug approvals

46. Apart from the above approvals which were considered controversial by the Hon'ble Parliamentary Standing Committee, there was mention of three more drug approvals in its 59th report which the Committee could not scrutinise as the files were missing. The Hon'ble Committee was suspicious about the disappearance of these files as they pertained to three controversial drugs (pefloxacin, lomefloxacin and sparfloxacin).
47. Since the three files were missing, the Hon'ble Committee ordered the files to be reconstructed and reviewed to determine if all conditions were followed before granting approval. In its final ATR, the MOHFW informed the Hon'ble Committee that although the files were reconstituted some details were still unavailable and that all three drug approvals would be referred to a New Drug Approval Committee (NDAC) for review.

48. The Petitioner humbly submits to this Hon'ble Court that 'missing files' in a government department is usually an indicator of corruption, incompetence or a cover-up. Such missing files also indicate that the government department is not complaint with the Public Records Act, 1993. In the present case, neither the MOHFW nor the CDSCO have bothered to investigate how such sensitive files went missing. The petitioner has confirmed that no such investigation was ordered by filing an application under the RTI Act, through his advocate. In this RTI application, the MOHFW was asked whether a FIR was filed with the police or whether any internal investigation was conducted by the CDSCO itself to determine the manner in which the three files were lost. The replies from the MOHFW and the CDSCO confirms that no FIR was filed and no investigation was conducted by either the MOHFW or the CDSCO. It is a matter of great concern that the CDSCO and the MOHFW did not think it necessary to conduct so much as an internal enquiry after they discovered that three sensitive files had gone missing.

IV. Report of the Expert Committee setup to suggest recruitment rules/job description for senior level posts in Central Drugs Standard Control Organisation

49. In its 59th Report, the Hon'ble Parliamentary Standing Committee had recommended to the Government that it have a relook at the qualification criteria for the top posts of the CDSCO, including the position of DCG(I). In particular,

the Hon'ble Committee stressed on the fact that it was important for the drug regulator be headed by a medical doctor who had experience in the practice of medicine and research. In particular the Hon'ble Committee was against appointing persons with only a degree in pharmacy as the DCGI. In relevant part, the Hon'ble Committee pointed out that drug regulators in most developed countries like the US & EU were headed by medical doctors and not pharmacists. Subsequent to the Hon'ble Committee's recommendation in 2012, the MOHFW setup an expert committee two years later on 03.03.2014 consisting of the Former Secretary DoPT, Former Secretary Department of Biotechnology and a Prof. Emeritus of Pharmacology and two former DCG(I)s. This expert committee submitted its final report to the MOHFW on 1st June, 2015.

50. The Petitioner humbly submits, with all due respect to this Committee, that the final report of the committee has completely failed to address the main concern of the Hon'ble Committee, which is to examine whether a person with a bachelor's degree in pharmacy is qualified enough to head an institution like the CDSCO which makes decisions to approve new drugs or new clinical trials for Indian patients. In doing so, the Expert Committee fails to understand the main thrust of the Hon'ble Standing Committee's recommendation, which is the fact that the persons with Degrees in Pharmacy simply lack the training

to make complex decisions such as the approval of new drugs or conduct of new clinical trials.

V. Other Recommendations of the Expert Committee headed by Dr. V. M. Katoch

51. After the tabling of the scathing report of the 59th Parliamentary Standing Committee report, the MOHFW quickly announced the formation of an Expert Committee headed by Dr. V.M. Katoch who was the Director General of the Indian Council of Medical Research (ICMR) and comprising also of Dr. P.N. Tandon who was then the President of the National Brain Research Centre, Manesar and Dr. S.S. Agarwal the Former Director of Sanjay Gandhi Postgraduate Institute for Medical Sciences, Lucknow. Some of these committee's recommendations are already discussed above in context of the illegal approvals granted by the CDSCO. In addition to the recommendations already discussed, there are other important recommendations of the Committee which are yet to be implemented by the CDSCO. In particular the committee had "recommended that a consultant/consultancy shall be commissioned to carry out the following activities" (which are hereby extracted below):

"a) Review of implementation of the Mashlkar Committee report with a view to identify items implemented and those in the pipeline; the likely timeframe of their implementation and decisions on remainder recommendations;

b) Study of international role model/s in the field of drug regulation to identify qualitative changes that Indian regulatory system should adopt in its functioning;

c) Study of the self-assessment report of the CDSCO and make critical appraisal of it in context of (i) and (ii) above.

d) Carry out in-depth ‘wet’ study of the current structure and functioning of the CDSCO, including newly constituted NDACs, employing work-motion studies, individual and group interviews and other techniques of qualitative research;

e) On the basis of the above studies the consultant/consultancy shall prepare a blueprint of structure and functioning of CDSCO, with identification of inputs, implementation programme and outcome of revamping – with clear cut goals and timelines;

f) The report so prepared should be critically appraised and accepted by the Government.”

52. It is humbly submitted to this Hon’ble Court that the petitioner through his advocate filed a RTI application with Respondent No. 1 to determine whether any of the above studies recommended by the Katoch Committee were in fact commissioned. In a reply dated September 17, 2015 the Respondent has confirmed in a reply that no such study was commissioned by it.

VI. CREATING A NATIONAL SEARCHABLE DIGITAL DATABASE CONSISTING OF ALL NSQ REGISTERS & PROSECUTION REGISTERS MAINTAINED BY ALL DRUG INSPECTORS ACROSS THE COUNTRY

53. One of the principal problems faced by both the medical community and patients/consumers today is the lack of a national database of NSQ drugs along with the names of the manufacturers responsible for manufacturing those drugs. Such a database would help both doctors and patients access information which would help establish the credibility of various drug manufacturers. In its 59th Report, the Hon'ble Standing Committee had pulled up the MOHFW on the lack of such a database. In the Action Taken Report (ATR), the MOHFW admitted to the problem and informed the Hon'ble Committee of a number of e-governance measures that it was taking on its part to ensure easy accessibility of information. Since that report, a few states have been publishing details of NSQ drugs detected in their individual states, while other states have collaborated with the Central Government to post all NSQ drugs on the XLN website. The problem however is that the database is limited to only a few months data. Further not all states are uploading their information onto the database.

54. The key focus of the XLN database appears to be aimed at making it easier to issue licences to manufacturers. Public health is not the focus of the XLN database, it is only a secondary objective. In order to ensure the creation of a

database which actually informs the medical profession and patient community, the entire format of the website has to be changed. As of today, most state drug controllers maintain at least two Registers, called the Register of NSQ drugs and Register of Prosecutions. As the name suggests, the NSQ register maintains a list of all NSQ drugs notified by the state laboratory, while the Register of Prosecutions maintains a list of prosecutions initiated by each Drug Inspector and often also includes details regarding the outcomes. For example while states like Karnataka, Gujarat and Maharashtra maintain a centralised Register for the entire state, other states like Tamil Nadu maintain Registers at the District level. In order for the medical community to properly evaluate the credibility of a particular manufacturer before the prescribing their medicines, it is necessary to create a database consisting of at least 5 years of data from each and every state drug controller, state laboratory and central laboratory. Such a database should be digitised and accessible on the internet, to any citizen of India in multiple languages and at no cost.

D. LACK OF INVESTIGATION BY THE CDSCO INTO THE RANBAXY SCANDAL & OTHER CASES DETECTED BY FOREIGN REGULATORS

55. As has been well established by the earlier responses received from the MOHFW to the petitioner's RTI applications, the MOHFW and CDSCO are most reluctant to

investigate possible violations of the law by pharmaceutical companies despite the fact that the said violations have seriously endangered the lives of Indian citizens. Apart from the aforementioned scandals uncovered by the Hon'ble Parliamentary Standing Committee, the petitioner would also like to bring to the attention of the Hon'ble Court, other important scandals which required to be investigated under the supervision of the Hon'ble Supreme Court. The details of these scandals follow below:

(a) The Ranbaxy Scandal: As explained earlier in this petition, Ranbaxy Laboratories Ltd. ("Ranbaxy") and its American subsidiary ("Ranbaxy USA") agreed to pay approximately $500 million in cumulative penalties, damages & costs to the US Federal Government, State Governments in the US and the Petitioner, after both civil and criminal action was initiated against the company on the basis of information provided by the Petitioner in his capacity as a whistle-blower. The Petitioner had collected this information during his employment at Ranbaxy in its Indian offices, where he tried to convince the management to take corrective action. After failing to convince the management to take corrective action, the Petitioner resigned and submitted the information to the relevant authorities in the US. After news of Ranbaxy's settlement broke in India, several people in the Indian medical community had raised concerns because all of Ranbaxy's

manufacturing facilities that were indicted were located in India and were supplying medicine to Indian citizens. Eventually the matter reached Parliament, when Hon'ble MPs raised questions during 'Question Hour'. The then Minister of Health Ghulam Nabi Azad on August 6, 2013 had informed the Rajya Sabha that the DCGI had already been ordered to review the GMP Compliance of the manufacturing facilities of Ranbaxy.

56. Since the Petitioner was the whistle-blower whose actions led to the prosecution of Ranbaxy, the Petitioner was expecting to be contacted by the relevant authorities in India to aid with the investigation. However when he didn't hear from any of the authorities almost 2 years after the Minister's statement, he instructed his advocate to make the necessary enquiries to determine the status of the investigation. The Petitioner's advocate filed an application under the RTI Act with the MOHFW on April 7, 2015 asking for the status of the investigation into Ranbaxy's facilities. This application was transferred to the CDSCO which eventually replied to the Petitioner's Advocate on July 6, 2015. The CDSCO provided a copy of a letter from the MOHFW dated June 11, 2013 where the Director, MOHFW instructed the DCGI to "review the GMP Compliance of the above referred two manufacturing facilities of Ranbaxy in India as well as to ascertain the safety, quality and efficacy of drugs manufactured for the domestic market in these

facilities, particularly during the period in question." The CDSCO however refused to provide a copy of the final report of the DCGI after inspection of Ranbaxy's plants on the grounds that the Section 8(1)(h) of the RTI Act exempted from disclosure information that would impede ongoing exemption and also on the grounds that such information would be considered secret/commercial information exempt under Section 8(1)(d) of the RTI Act.

57. On receiving the above reply from the CDSCO, the petitioner's advocate filed another RTI application with the MOHFW asking it whether permission had been granted to the DCGI to outsource the enquiry to SLAs, whether the DCGI was requested to hasten the enquiry and whether Ranbaxy had been asked for an explanation into the circumstances behind the penalty imposed on it in the US. The MOHFW replied in the negative to all three queries. The above replies reveal the degree of apathy and confusion within the Government of India on the issue of wrongdoing at Ranbaxy, once the country's largest drug company.

58. <u>(b) Failure to act on investigation reports by foreign regulators</u>: It is humbly submitted to this Hon'ble Court, that ever since the Ranbaxy scandal came to light, foreign regulators stepped up their scrutiny of Indian drug manufacturers. The increased scrutiny revealed a series of dangerous lapses of Good Manufacturing Practices (GMPs) amongst Indian manufacturers. GMPs were incorporated

into Indian law via Schedule M to the D&C Act in the year 2001. These GMP standards are based on guidelines laid down by the World Health Organisation (WHO) and are almost similar across the world. Amongst other requirements, these standards require manufacturers to maintain records in a certain format for a certain time period and also follow certain protocols to ensure that the manufacturing and packaging activities are carried out in a sterile environment. Both these requirements have been found to be regularly flouted by Indian manufacturers. As per the knowledge of the Petitioner, a total of 44 manufacturing plants are prohibited from exporting to developed countries like the USA because they have been found to be in violation of GMPs. It is disturbing that it took a foreign regulator to discover these glaring lapses in Indian plants. Similarly, when Vietnam blacklisted over 46 Indian companies for the supply of NSQ drugs to that country, no action was taken by the CDSCO against those companies almost two years after the blacklisting by the Vietnamese. When the Petitioner through his advocate requested the CDSCO to inform him of the status of the investigations, the CDSCO once again claimed that SLAs were conducting the investigation and no information could be provided to the petitioner. It is now common for CDSCO to not conduct detailed investigations into lapses pointed out by foreign regulators. This is contrary to established international

practices when it comes to safety of food and drugs. For example, when India detected certain safety issues with Maggi ® noodles manufactured by Nestle, international regulators in the US and Europe took the information seriously and conducted their own tests on the product to determine the safety of the same. The CDSCO rarely follows such an approach as can be determined from the response provided by the regulator to a RTI application filed by the petitioner's advocate.

59. In this RTI application filed on April 6, 2015 the petitioner's advocate asked the CDSCO whether it had inspected the plants of Apotex India or IPCA after 'Health Canada' the Canadian drug regulator had imposed import bans against imports from manufacturing plants of these companies based in India because of GMP lapses. The CDSCO replied with the following answers:

Point No. A
For drugs meant for export to other countries approval for marketing in their country are granted by the regulatory authority of the importing country. Health Canada issued permission for marketing the drugs in Canada after evaluation of the facilities and verifying compliance as per the requirement laid down by it. There is no agreement on requirement that CDSCO communicates with Health Canada when a ban is imposed on products manufactured by the firms registered with Health Canada.
Point No. B
Licenses are issued by the State Licensing Authorities and inspections are conducted periodically. CDSCO headquarters has not conducted any inspection with respect to the alleged ban imposed by Health Canada.

60. The above reply by the CDSCO flies in face of circular no. DCG(I)/MISC/2013(87) issued by the DCGI on June 26,

2013 ordering all state regulators to inform all manufacturers that they are required to inform the DCG(I) and the state authorities of any foreign regulatory action initiated against them so that Indian authorities can assess the impact of the lapses on Indian patients.

E. NO COMPULSORY REQUIREMENT FOR MANUFACTURERS OF GENERIC DRUGS TO CONDUCT BIOEQUIVALENCE & STABILITY STUDIES FOR DOMESTIC SALES WITHIN INDIA

61. The petitioner humbly submits to this Hon'ble Court that one of the principal reasons for such a large number of NSQ drugs in the Indian market is because Indian law doesn't prescribe rigorous testing prior to granting approval for the sale of generic drugs in India. As explained earlier in this petition, new drugs, which have never been approved earlier (as defined in Rule 122E of the Drugs & Cosmetics Rules, 1945) require to be approved by the Central Licensing Authority which is the CDSCO. While granting approvals for such new drugs, Schedule Y along with Appendix I of the Drugs & Cosmetics Rules, 1945 require the licensing authority to scrutinise clinical trial data before granting marketing approval. As per Rule 122E, a 'new drug' ceases to be 'new' after a period of 4 years and areno longer regulated by the CDSCO. The sole authority for granting licences for manufacture and marketing for drugs which have lost their 'new drug' statusare State Licensing Authorities (SLA). The rules and regulations followed by

these SLAs while granting approval to such drugs are however completely outdated when compared to other advanced jurisdictions in the world.

62. In most countries, like the US for example, the first company to discover a new drug (hereinafter ‘innovator drug’) will have to conduct extensive clinical trials on patients over three phases and collect data to demonstrate that the drug is safe and effective for human use. Thereafter, depending on the patents covering the drug in question, other manufacturers may enter the market to manufacture what are known as generic drugs. These generic drug manufacturers aren’t required to replicate entire clinical trials in order to get approval for their drugs. However such generic drug manufacturers are required to mandatorily conduct studies to establish that the drug formulations manufactured by them are bioequivalent to the innovator drug. Bioequivalence studies are designed to prove that the generic drug is in fact the therapeutic equivalent to the original drug which has already been approved in the market. These bioequivalence studies are usually conducted on healthy humans by administering the generic drug on them and then observing various factors, one of them being the rate at which the drug dissolves in the subject’s bloodstream. If the generic drug has the same effect on the human body as the innovator drug, it is said to be bioequivalent to the innovator drug. Proof of

bioequivalence establishes the fact that the generic manufacturer has the capacity to manufacture the drug in question and that such a drug is interchangeable with the original drug that has been approved after extensive clinical trials.

63. Similarly, stability studies are considered important in most countries to ensure that the formulation can survive over long durations of time and in different weather conditions without the active ingredient losing its potency.

64. The importance of bioequivalence and stability studies is recognised by the CDSCO/Respondent No. 2 since it requires such data to be submitted before it grants marketing approval to ‘new drugs’ as defined in Rule 122E. Submission of such data is compulsory under Schedule Y, Appendix I and Appendix IX, both of which clearly require such studies to be conducted by any applicant seeking to manufacture the drug while it is in the ‘new drug’ status. The ‘new drug’ status however expires after a period of 4 years and that is where the problems begin.

65. Under Indian law once a drug loses the ‘new drug’ status after 4 years, the task of licensing is done exclusively by the State Licensing Authority (SLA). As of now, the Drugs & Cosmetics Act does not require the submission of any BE/BA or stability studies from manufacturers who are applying directly to the SLA after the 4 year mark for ‘new

drugs' has been crossed. This problem has been brought to the attention of the government in the past but Respondent No. 1, 2 and 3 have declined to act on incorporating such a requirement into Indian law because of profitability concerns. The first recommendation for mandatory BE/BA studies was made in the Report of the Prof. Ranjit Roy Chaudhury Expert Committee which had recommended in July, 2013 that Bioequivalence and Bioavailability studies be made compulsory for all generic drugs that are sought to be marketed in India. The Respondent No. 1 considered this recommendation of the Expert Committee and expressed concern that such a requirement would have an impact on the industry due to increased cost, longer timelines in granting licences and also concerns over the availability of infrastructure to conduct such studies. The Ministry thus decided to hold wider consultations with all stakeholders. Thereafter, this issue was discussed in the 4^{7th} Meeting of the Respondent No. 3 held on 3^{0th}& 3^{1st} July, 2014. After considering the proposal of the Expert Committee, Respondent No. 3 rejected the recommendation of the Expert Committee purely on the grounds that it would hurt the profitability of the industry. In pertinent part, the Report of the 4^{7th} meeting states: "The recommendations of the Prof. Ranjit Roy Chaudhury Committee in respect of Bioavailability or Bioequivalence (BA / BE) studies conducted in India were deliberated in detail. The members

were of the view that BA / BE studies in respect of drugs manufactured in the country shall be insisted whenever there are issues relating to patient safety and variable bioavailability. As the infrastructure for conduct of such studies is not uniformly available in the country it cannot be implemented as a rule." This assertion by Respondent No. 3 is patently false because India has had one of the largest and most successful Clinical Research Organisation (CRO) business in the world.Moreover, in the very same report Respondent No. 3 reiterates that such BA/BE studies should be carried out in the case of exports failing which exports would decline. In pertinent part, the 47th Report states "In the case of BA / BE studies for export purposes such studies may be permitted as per requirements. The growth of the Indian Pharma Industry in terms of exports is declining in the last few years and any embargo on BA / BE studies on substances discovered abroad and not marketed in India would further decline the exports." This particular report of Respondent No. 3 demonstrates how different standards of safety are adopted for the domestic market and the export market.

66. Similarly in the Report of the 46th Meeting of the DCC/Respondent No. 3 held on 12th and 13th November, 2013 the DCC/Respondent No. 3 discussed the need to introduce a mandatory requirement to carry out 'stability testing' for even those manufacturers seeking entry into the

Indian market after 4 years and unanimously recommended that the Rules be amended to make such testing mandatory for even those manufacturers entering the market after 4 years. Such amendments have not yet been carried out in India as a result of which unstable drugs are most likely being manufactured across the country.

F.THE "GUIDELINES FOR TAKING ACTION ON SAMPLES OF DRUGS DECLARED SPURIOUS OR NOT OF STANDARD QUALITY IN THE LIGHT OF ENHANCED PENALTIES UNDER THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008"

67. In the year 2008, Parliament enacted the Drugs & Cosmetics (Amendment) Act, 2008 with the intention of strengthening the drug regulatory system in India along with providing harsher punishments for persons caught selling spurious drugs. A few months after the enactment of this amendment, there were news reports that the pharmaceutical industry associations were demanding that the DCG(I) issue legally binding guidelines to all State Drug Controllers in order to ensure that the more stringent provisions of the law were not misused against the industry. A few months after these announcements, the DCG(I) finalised certain guidelines titled "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008". ("Guidelines") These Guidelines were circulated to all state

drug controllers with directions to follow them in order to ensure compliance.

68. The basic objective of the Guideline is to create three different categories of drugs and guide State Drug Controllers on how exactly to prosecute drugs which fail randomised testing in Government Laboratories: **Category A (Spurious and Adulterated Drugs), Category B (Grossly sub-standard drug) and Category C (Minor Defects)**. These categories are explained below:

Category A: This category covers spurious and adulterated drugs. As per these guidelines, spurious drugs are those where the identity of the true manufacturer is hidden and the drug is sold under a well- known brand name so as to knowingly deceive customers. Such drugs may or may not have the active ingredient. Adulterated drugs are classified as those which are found to contain an adulterant/substituted product or contaminated with filth rendering it dangerous for public health. The guidelines recommend vigorous prosecution for all cases that fall within Category A.

Category B: This category covers only grossly "sub-standard drugs". As per the guidelines, these are those drugs manufactured by licenced manufacturers and are reported to have defects of serious nature to affect the quality of drugs. A few examples of such defects are: (i) API is below 70% for thermos liable and below 5% of the

permitted limits for thermos stable products; (ii) Tablets/capsules failing in disintegration tests wherever prescribed. (iii) Tablets/capsules failing in dissolution test; (iv) Failure of sterility and other tests (v) presence of adulterant which renders the product injurious to health. For all these cases that fall in Category B, the guidelines recommend that the weapon of prosecution should be used judiciously and administrative measures like suspension of licences etc. should be preferred or compounding of offences.

Category C: This category covers only “minor defects”. A few examples of such defects are as follows: (i) Broken or Chipped tablets (ii) Presence of spot/discolouration (iii) Cracking of emulsions (iv) Clear liquid preparations showing sedimentation (v) Slight variation in net content. For cases that fall in Category C, only administrative measures and compounding of offences are recommended. Prosecutions are to be used only as a last resort when the former measures may not work.

69. These guidelines prescribe vigorous prosecutions only in case of Category A. For category B, which is perhaps the biggest problem in the Indian industry, the guidelines state that the weapon of prosecution should be used only judiciously and only in cases where criminal intent or gross negligence is established. Similarly with Category C, the guidelines recommend administrative measure or

compounding of offences, with prosecution being the last resort. As a result of these guidelines an overwhelming number of NSQ drugs are not prosecuted in criminal cases since State Drug Controllers only impose minor administrative penalties on the offenders. For example, in a RTI response to the petitioner's advocate, the Food & Drugs Control Administration of Gujarat stated that it did not prosecute a single one of the 216 cases of NSQ drugs detected by it between October, 2014 and April 2015.

70. Apart from guiding State Controllers on prosecutions, the categorisation laid down by these Guidelines also play an important role in the blacklisting or deregistration of firms participating in public procurement of medicine for the Central Government. In the *Procurement and Operational Manual for Medical Store Organisation and Government Medical Store Depots* which is published by the Directorate General of Health Services (DGHS), MOHFW and which governs the procurement procedure for all Medical Supply Organisation (MSO) under the Central Government which supplies the Central Government Health Scheme (CGHS), the classification of Category A and Category B as described in the aforementioned Guidelines is copied verbatim. The procurement guidelines, or more precisely Supply Form MSD-0905 provide for a graded penalty system depending on the nature of defects found. If a firm is found to be supplying drugs which are found to have

Category A defects, the supplier is debarred from supplying the same product for three years. Similar penalties operate in case of Category B defects. Category C is not mentioned in this Manual.

71. These Guidelines are in complete contradiction to the scheme of the Drugs & Cosmetics Act, 1940. Section 16 of this Act mandates that all drug manufacturers follow standards laid down in Schedule II to the Act. This Schedule requires all manufacturers of allopathic drugs to follow standards laid down in the Indian Pharmacopeia (IP). The IP is published by the Indian Pharmacopeia Commission (IPC), an expert, autonomous body constituted by the Ministry of Health & Family Welfare (MOHFW) for this very purpose. For drugs which are not included in the IP, the standards laid down in the pharmacopoeias of other countries can be followed. The IP lays down standards, including permissible deviations. The Pharmacopoeias contain directions to identify different chemical entities in different medicines and will also specify the properties required to be possessed by each compound. When drug samples drawn from the market by drug inspectors are sent to a government laboratory, the government analyst will test each sample on the following three factors: (i) content of the active ingredient (ii) dissolution rate (iii) disintegration rate. In addition, the analyst will also consider a visual examination of the tablets, capsules or liquid to note for any discolouration or

sedimentation. The IP provides the permissible standards by which the content of active ingredient may differ – a 10% margin of error on whatever is mentioned on the labelling of the medicine is usually acceptable. Similarly the IP documents the time frame within which a sample must dissolve or disintegrate in a particular medium. Likewise, the visual description of the medicine will have to comply with the standards laid down in the IP because if a drug is not as per the colour specified in the IP, it is likely that it has not been manufactured as per established norms. All of these standards laid down by the IP have to be followed by the manufacturer in order to ensure that the medicine is of standard quality. If the content of the active ingredient varies beyond what is deemed acceptable by the IP too much, or if the dissolution rate or disintegration rate is not as per standards laid down in the IP, it is entirely likely that the drug will fail to have the intended therapeutic effect. Similarly if a drug has the correct amount of active ingredient but doesn't dissolve or disintegrate within the specific time or quantity, the drug will not have a desired effect on the disease. Also if the drug disintegrates or dissolves as per the standards in the IP but fails to have enough active ingredient the drug will not have the expected therapeutic benefit.

72. Any violation of the standards laid down in the IP, will result in the Government Analyst classifying the drug as being Not

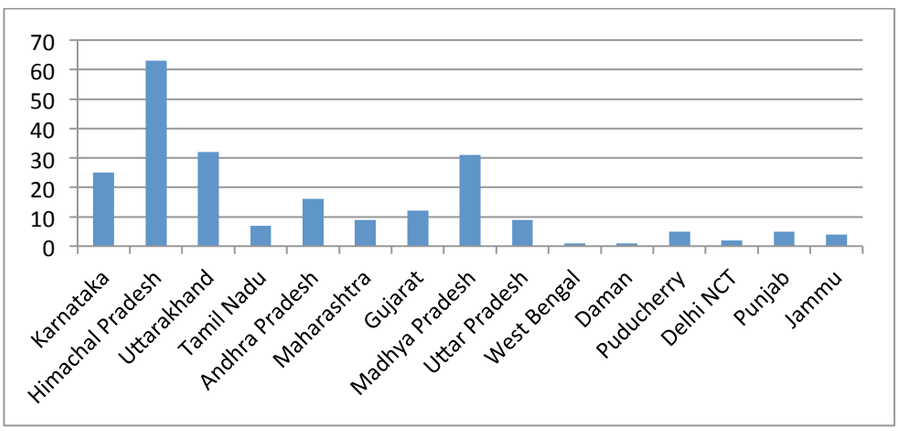
of Standard Quality (NSQ) and the drug inspector may prosecute the manufacturer under Section 18(i)(a) read with Section 27(d) of the D&C Act, which is a residuary provision that provides for the prosecution of offences not defined in the D&C Act. However because of the Guidelines described above, most deviations from the standards laid down in the IP are not prosecuted.

G. LACK OF UNIFORMITY IN ADMINISTRATIVE ACTIONS TAKEN BY DIFFERENT SLAS AGAINST MANUFACTURERS OF NSQ DRUGS

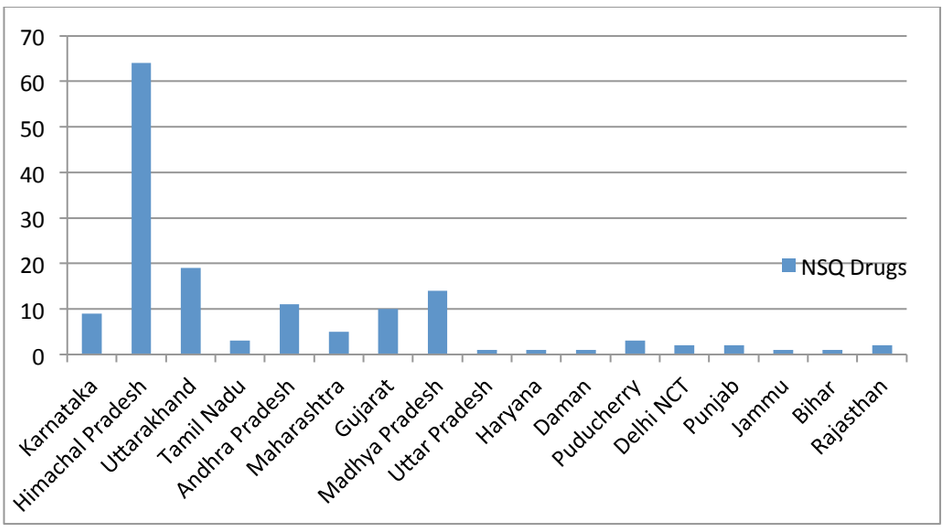
73. Apart from the process of criminal prosecution to punish violators of the D&C Act, the Drugs & Cosmetics Rules, 1945 also provide for punishments in the form of others measures which could include the Controller suspending or cancelling the manufacturing licences of the company found to have manufactured NSQ drug. The relevant rule in this regard is Rule 85-I, and this power is exercised by Drug Controllers in individual states, since it is State Governments and not the Central Government which licences drug manufacturing in India. This Rule states that the licensing authority may after giving the licensee an opportunity to show cause why such an order should not be passed, cancel a licence issued or suspend it for such period as he thinks fit either wholly or in respect of some of the substances to which it relates.

74. As explained earlier in this petition, criminal prosecutions are relatively rare in India and most licensing authorities prefer to merely suspend licences as punishment for violation of the D&C Act. The problem however is since each SLA operates independently of the other there is no uniformity in the duration for which licences are cancelled. In order to establish this discrepancy, the petitioner through his advocate procured, under the RTI Act, copies of the Register of NSQ drugs maintained by the Karnataka Drugs Control Department (KDCD). This Register contains details of all the NSQ drugs detected by the KDCD within the state of Karnataka and the action taken against them. Since a majority of the NSQ drugs were actually being manufactured outside the state, the KDCD did not have the power to suspend or cancel licences for most of these manufacturers.

75. Below is a graphical representation of the states from which the KDCD detected NSQ drugs in the year 2012-13.



76. Below is another graphical representation of the states from which the KDCD detected NSQ drugs in the year 2011-12.



77. The two states accounting for the largest number of manufacturers of NSQ drugs every year in Karnataka are Himachal Pradesh and Uttarakhand, with Madhya Pradesh coming a close third. In such cases, where manufacturers of NSQ drugs are located outside the state, the KDCD would communicate with the State Licensing Authority (SLA) located in the home state of the manufacturer where the NSQ drug was manufactured. In response, the 'home' SLA would suspend or cancel the licence of the manufacturer and inform the KDCDA of the duration for which the licence was suspended. From the details contained in the Registers, it is quite obvious that there is no consistency amongst different states in the manner in which licences are suspended. For example while states like Himachal Pradesh, suspend licences from anywhere between 15 days to 3 months, states like Uttarakhand would suspend licences for a mere 20 days while a state like Gujarat would suspend licence for just 1 day. To the best of knowledge of

the Petitioner, this large scale discrepancy in the duration for which licences are suspended in different states is because there are no rules notified by the MOHFW under the D&C Act requiring all SLAs to follow uniform standards while suspending licences. Thus each SLA appears to exercise its own discretion while suspending licences.

78. A second issue with the practice of suspending licences is whether SLAs actually enforce their orders suspending licences and the consequences for manufacturers who continue to manufacture drugs that are not of standard quality even though their licences have been suspended. The petitioner has been unable to find any law or guideline on this point. The petitioner did file RTI applications through his advocate asking a few SLAs the following questions: "*What is the procedure followed by the Controller while deciding appropriate legal action when a sample is detected to be of 'Not of Standard Quality'? Does the Controller initiate criminal prosecution in all cases or is suspension of licences enough? The PIO is requested to please provide the applicant with a copy of procedure/rules to be followed while deciding appropriate legal action in such cases.*" The response provided by most SLAs was vague. For example, the Department of Drug Control Administration, Tamil Nadu provided the following answer "On the basis of the investigation report of the Inquiry Officer and also keeping the interest of the consumer in mind decision is being

taken”. Two other SLAs, in Maharashtra and HP simply stated that they follow guidelines laid down by the DCGI/CDSCO (these are presumably the Guidelines referred to earlier in the petition). While HP stated it had no guidelines of its own, Maharashtra claimed to follow its own guidelines, although no copy of the same was provided to the petitioner’s advocate. Apart from the fact that there are no guidelines or rules on enforcing the suspension of licences, the Petitioner also noticed that there are virtually no reported judgments on the issue of suspension of licences from the High Court of Himachal Pradesh despite the state being the largest source of NSQ drugs in the country and the SLA reporting to its counterparts in other states that it regularly suspends licences. While this finding is not conclusive in itself, it does cause one to question whether, the suspension of licences are being strictly enforced by SLA.

H. THE NEED FOR A UNIFORM NATIONWIDE STANDARD OPERATING PROCEDURE FOR DRUG INSPECTORS CONDUCTING INVESTIGATIONS INTO NSQ DRUGS

79. One of most significant problems regarding the enforcement of the D&C Act is the poor investigation and prosecution of NSQ drug manufacturers by Drug Inspectors who are appointed by both the Central and State Government. The Hon’ble Bombay High Court in the case of *Shivkumar* v.

Food & Drugs Administration, State Of Maharashtra MANU/MH/0588/2010, made the following scathing observations against the Maharashtra Food & Drug Administration after scrutinising an investigation conducted by it:

I conclude that the Food and Drugs Department and its officers right from the cadre of Food Inspectors to Joint Commissioner do not have any legal knowledge, legal skill and seriousness with which the provisions of these Acts concerning human health is required. They are casual, callous and hardly concerned. Relevant and concerned provisions/amended provisions of Code of Criminal Procedure are not even known to them to make use thereof. They are making cases only to show that cases are being prepared and instituted in courts and finally tell the people that courts have discharged or acquitted the accused persons and thus save their skin. In my opinion, Government is simply wasting money on Food and Drugs Department and serious view for revamping this department will have to be taken by the Government with strict `accountability' to be fixed for each and every officer.

80. Similar comments have been made by the Hon'ble Delhi High Court in the case of *Biochem Pharmaceutical and Ors.* v. *State* 121 (2005) DLT 207. The Hon'ble High Court made the following observations against the Drugs Control Department:

"23. Before parting with the case I must express my concern about the conduct of the complainant/Drug Inspector, on account of whose failure to take appropriate steps by getting the sample tested again in the Central Laboratory, the prosecution has failed. In case the manufacturer is innocent, the proceedings have resulted only in his harassment. On the other hand, if the drug was actually sub-standard the omission of the Inspector has resulted in the manufacturer escaping the clutches of the law and in encouraging manufacturing of substandard medicines which is dangerous to public health. The Drug Control Department, Govt. of NCT of Delhi is advised to take care to set its own house in order to ensure that such omissions on the part of the Drug Inspectors do not take place in future. Copy of the

judgment be sent to the Head of the concerned department."

81. In order to examine the manner in which prosecutions are conducted in India, the petitioner through his advocate, procured copies of criminal complaints filed by drug inspectors in the States of Andhra Pradesh and Tamil Nadu. From a simple reading of the criminal complaints it is obvious that the criminal complaints filed by drug inspectors are woefully inadequate when compared to the more thorough criminal complaints filed by their counterparts in Tamil Nadu. The first illustrative example is the criminal complaint filed by the Drug Inspector from the Vizianagaram District of AP against Quest Laboratories Pvt. Ltd. located in the state of Madhya Pradesh. In this case the state laboratory confirmed on 20th July 2011 that the sample sent to it by the drug inspector from Vizianagaram district was NSQ. Thereafter it took the Drug Inspector almost one year to file a criminal complaint against Quest Laboratories Pvt. Ltd. because the company never responded to any of the notices to produce relevant documents. In such a case, the Drug Inspector should have contacted his counterparts in either the CDSCO or the state of MP to raid the premises of Quest Laboratories. Similarly in the second illustrative example, the drug inspector had picked up from a pharmacy in Bhimavaram district, a sample of a drug manufactured in China by M/s QuzhouWerong Pharmaceuticals and Chemicals Co. Ltd. The drug had been imported into the

country by a Bombay based entity called Medipharma Drug House. When the state laboratory confirmed that the drug sample was NSQ, the drug inspector initiated an investigation by writing to the importer asking for an explanation. The importer denied that it had imported the drug and thus the Drug Inspector did not investigate the importer's claim and merely prosecuted the pharmacy. Since imports are regulated by the Central Government, the Drug Inspector should have ideally contacted the CDSCO's drug inspectors and verified the claim of the importer. The final criminal complaint filed in this case did not even mention the fact that the drug sample was imported from China. A third illustrative example, again from Andhra Pradesh pertains to a drug sample manufactured by Sun Pharmaceutical Industries (J&K) and the second by Zydus Healthcare (Sikkim). Both these samples were drawn by a Drug Inspector from a pharmacy in Machilipatnam District (AP) and both samples failed quality tests. In the subsequent investigation the Drug Inspector travelled to both J&K and Sikkim to collect more details from the manufacturers. In their meetings both companies, denied that they had manufactured the samples in question and the drug inspector seems to have accepted their explanation without fully explaining the reasons in the subsequent criminal complaint filed against the pharmacist who was selling these drugs.

82. In contrast to these three examples from the state of AP, the Petitioner has also procured two criminal complaints filed by Drug Inspectors in Vellore district of Tamil Nadu. Both criminal complaints are thorough on points of facts and law thereby demonstrating that there is a vast difference in the manner in which criminal prosecutions are conducted in the states of AP and TN. The need of the hour is therefore to have a standard operating procedure for all drug inspectors across the country while they are investigating cases under the Drugs & Cosmetics Act, 1940.

I. MINIMUM MANDATORY PUNISHMENT UNDER DRUGS & COSMETICS ACT ROUTINELY IGNORED BY SESSION JUDGES

83. Given the grave consequences posed to public health due to the consumption of NSQ drugs or spurious drugs or adulterated drugs, the D&C Act mandates certain minimum term of imprisonment which have to be adhere to by all judges during sentencing except in certain cases where judges may sentence a person for a duration, less than the mandatory minimum. It is important to understand that this was not always the case with the D&C Act. As originally enacted in 1940, the penal provisions of the D&C Act such as Section 27 & 28, used the following phraseology – “shall be punishable with imprisonment which may extend to one year, or with fine which may extend to five hundred rupees, or with both.” Thus the law in 1940 only prescribed the maximum duration for which a person may be imprisoned.

In 1960 however, these penal provisions were amended to read as follows – “shall be punishable with imprisonment for a term which shall not be less than XXX year but which may extend to XXX years”. A proviso was inserted to allow the Court to reduce the imprisonment below a year for special reasons. The change in the wording of the language clearly indicates that Parliament wanted to ensure that offenders under the D&C Act were required to be imprisoned for a minimum period.

84. It is humbly submitted to this Hon’ble Court that this provision is followed more in breach since the default rule that is followed by several judges across the country is to imprison a convicted offender under the D&C Act until the rising of the court. The petitioner, through his advocate, has procured copies of 6 judgments delivered by the Special Court, (Economic Offences), Bangalore. In each of these 6 cases, the judge in charge reduced imprisonment from the minimum one year to simple imprisonment till the rising of the court because the accused either had family members depending on him/her or because the accused was suffering from medical conditions and had employees. The details are given below.

C.C. No.	**Case title**	**Reason for reducing sentence below mandatory minimum**
7/2014	Drugs Inspector v. Causway Pharma, Gujarat &Anr.	1. Accused had family members as dependants; 2. Accused had

		employees
291/2014	Drugs Inspector v. Surien Pharmaceuticals (P) Ltd. &Ors., Kovur	1. Accused had family members as dependants; 2. Accused had employees
01/2009	Drugs Inspector v. InjectoCaptaPvt. Ltd. &Ors., Secunderabad	1. Accused had family members; 2. Accused suffering from cardiac problem and diabetic;
400/2010	Drugs Inspector v. Quasar Labs Pvt. Ltd., Uttaranchal	1. Accused had family members; 2. Accused's mother was suffering from serious ailments;
136/2008	Drugs Inspector v. Sanchez Pharmaceuticals (P) Ltd. &Ors., Haryana	1. Accused had family members; 2. Factory was shut anyway.
134/2012	Drugs Inspector v. BRD Medilabs, Solan, Haryana &Ors.	1. Accused had family members; 2. Accused's mother was suffering from serious ailments;

85. In addition to the cases mentioned above, the petitioner draws the attention of the Hon'ble Court to "Conviction Register" maintained by Drug Inspectors in Karnataka and the Prosecution Registers maintained by different districts in Tamil Nadu. It is obvious from these Registers that persons convicted for the manufacture of NSQ drugs are routinely sentenced only "till the rising of the court" despite Section 27(d), the relevant penal provision clearly stating that a convicted person "shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less

than twenty thousand rupees." The proviso allowing for less than a year's imprisonment does exist, but the frequency with which convicted persons are being imprisoned till the rising of the court suggests that the proviso has become the norm rather than the exception.

J. MEASURES FOR REFORMING PUBLIC PROCUREMENT OF MEDICINES BY CREATING A CENTRALISED BLACKLISTING DATABASE AND FORMULATING UNIFORM BLACKLISTING GUIDELINES AMONGST ALL MEDICAL SUPPLY ORGANISATIONS THAT FUNCTION UNDER THE GOVERNMENT OF INDIA

86. One of the significant problems faced today in the public procurement of medicine by government agencies is the issue of poor quality of the drugs. The Public Accounts Committee (PAC) of the Lok Sabha, which is the chief parliamentary watchdog of public finances and the Comptroller & Auditor General (CAG) which is the chief constitutional watchdog responsible for auditing public expenditure, have both red-flagged the issue of quality of drugs being procured by public funds. These problems have been persistent and serious. For example, the CAG after an audit in 2007 pointed out serious problems with the quality of medicine being procured by the Medical Store Organisation (MSO) for the Central Government Health Scheme (CGHS), which caters primarily to public servants, including the Hon'ble Judges of this Supreme Court. In this report, which is the 20th Audit Report of 2007, CAG made two very relevant observations. It first noted that the Central

Government lacked a detailed procurement policy for drugs and that the 1979 Manual used by the government was outdated. The second relevant finding by CAG was the fact that the Central Government lacked a formal system to vet suppliers of drugs. The Public Accounts Committee (PAC) conducted its own hearings on the basis of the CAG report and tabled its findings in the 24th Report of the 15thLok Sabha on February 24, 2011. In this report, the PAC noted that the government was putting in place a new policy to deal with public procurement of drugs by its MSO and that it would conduct increased testing of drugs. In a follow up by PAC in its 84th report, which was tabled in Parliament on April 30, 2013, the PAC noted that the government had taken several steps including putting in place a new procurement policy and conducting increased testing. The PAC studied this subject, once again, in its 22nd report which was tabled before the 16thLok Sabha on August 13, 2015. In this report, the PAC report noted that sub-standard drugs were found to have been issued by CGHS Kolkata and Mumbai before test reports returned from the lab. The PAC demanded a probe to assess how such medicines go through the quality assurance mechanisms put in place by the MOHFW.

87. Similar issues have arisen in other CAG reports conducted on procurement by other Government entities like the Indian Railways and the Armed Forced Medical Services Depot. In

its report no. 28 of 2014, the CAG noted that there had been several instances where the Indian Railways was found to have issued medicines to patients and then later discovered that the drugs were NSQ because the lab reports came back only after the drugs were issued. In its Report No. 18 of 2012-13, CAG pointed out severe issues regarding the quality of drugs procured by the Armed Forces Medical Stores Depot (AFMSD). As is the case with the CGHS system and the Indian Railways, the AFMSD is also supposed to test each batch of drugs procure before the drugs are issued to patient. As pointed out by CAG in its report, very often such testing does not happen or even in cases when samples are sent for testing, they come back too late, after the drugs are already disbursed. For samples which were tested, the CAG report notes that the rate of rejection for locally procured medicine, due to samples failing quality tests, increased **from 15% to 31% during 2006-07 to 2010-11**. **The average rate of rejection during the three year period of 2008-09 to 2010-11 was therefore 24% approximately.** This means that one in every four drugs dispensed by these organizations is not of standard quality. This is a shockingly high rate of NSQ drugs which illustrates the scale of problem when drugs are procured locally from smaller companies in contrast to procurement by larger companies which appears to face lower rejection. As things stand today, the CGHS, the Indian

Railways and the AFMSD follow different processes to blacklist suppliers of sub-standard medicine.

88. It should be noted that in the coming years, that the Government will be spending more money on the procurement of quality generic medicine for its *Jan Aushadi* medical scheme which is expected to be the main source of medicine for a large percentage of the population in the country.

K. THE NEED FOR A NEW DRUG REGULATION LAW IN INDIA

89. As mentioned earlier in this petition, a study published in the highly respectable medical journal *Lancet* had recommended that India enact a new legislation to replace the "old and deficient" D&C Act which was enacted in 1940 and amended several times since then. In pertinent part, the article concluded with the following phrase "However, truly effective regulation equal to and necessary for India's major contribution to global drug manufacture will not happen without legislators with vision who see the need for a new Drugs Act. Such an Act should have clearly drafted rules requiring rigorous and transparent evidence that supports the effectiveness and safety of new drugs in the context of public need." This conclusion is supported by other findings which have been presented in this petition. The most authoritative commentary in this regard is the 59th Report by the Parliamentary Standing Committee on Health. The

Hon'ble Supreme Court has itself witnessed the abysmal regulation of clinical trial in an earlier PIL. The Government of India has however done precious little to correct the situation. Every standing committee report was met with vague promises of reform and at the most these reforms have consisted of mere band-aids when the need of the hour has been reconstructive surgery.

90. **As per Disclosure requirement under Order XXXVIII of the Supreme Court Rules, 2013 for petitioners in PIL cases, the following are the details of the Petitioner;**

A. **Name:** Dinesh Singh Thakur
B. **Postal Address:**
103 A, Thomas Prabhu Reliance Complex,
First floor, 3-6-278, Opp. Dr. P.Shiva Reddy Eye Hospital
Himayatnagar, Hyderabad Pin 500029
Telangana State

C. **Annual Income**: The petitioner received a payment of $48 million dollars in the year 2013 for being the whistle-blower in the case of *United States ex rel. Dinesh S. Thakur v. Ranbaxy USA Inc., et. al.,* Civil Action No. 1:07-00962-JFM (D. Md.) The petitioner, through his company Medassure Global Compliance Corporation, advises, pharmaceutical companies,international NGOs and aid agencies on issues relating to quality of medicines.
D. **Email:** dinesh.thakur@medassurecompliance.com
E. **Phone number:** +91.9818402188
F. **The nature and extent of personal interest, if any, of the petitioner(s):** None
G. **Details regarding any civil, criminal, or revenue litigation, involving the petitioner or any of the petitioners, which has or could have a legal nexus with the issue(s) involved in the Public Interest Litigation:**The petitioner was a plaintiff in the case of *United States ex rel. Dinesh S. Thakur v. Ranbaxy USA Inc., et. al.,* Civil Action No. 1:07-00962-JFM (D. Md.). This litigation before the United States District Court in

Maryland has been concluded after a settlement between all parties and a copy of the settlement agreement is annexed herewith. The petitioner received a payment of $48 million dollars from the penalty of US $500 million dollars imposed on Ranbaxy in the aforementioned case. This litigation pertains only to one of the issues raised in this petition, which is the failure of the Indian Government to adequately investigate Ranbaxy for failure to comply with quality standards. There are no other litigations in which the petitioner is involved against the pharmaceutical industry.

H. **Whether the concerned government authority was moved for relief sought in the petition and if so, with what result:** The petitioner on September 17, 2014 met the then Union Minister for Health Dr. Harsh Vardhan with a representation to urgently improve the quality of medicine in India and reform the CDSCO. A written letter to this effect was sent to the Minister on October 19, 2014. The Minister never replied to the petitioner. A true and correct copy of the letter sent by the Petitioner to the Union Health Minister with the representation dated 19.10.2014 is annexed herewith and marked as **ANNEXURE P-4**.

I. The petitioner also attempted to meet the Chairperson of the Quality Council of India (QCI) but was unsuccessful.

J. **The facts constituting the cause of action:** Are elaborated in PARAS 1-6, C-G of the petition.

K. **The nature of injury caused or likely to be caused to the public:** Are elaborated in PARAS 5-6, C-G of the petition.

L. The Petitioner submits that the details of his PAN Number are not disclosed in the Petition and a letter seeking exemption from disclosing the same in the Petition is filed along with this Writ Petition.

91. The Petitioner states that no other similar petition has been filed by him before this Hon'ble Court or any High Court or any other Forum.

92. **GROUNDS**

The present writ petition is being filed on the following grounds and without prejudice to one another:

(A) That the lack of a nationwide recall system for drugs, found to have failed quality standards laid down under Section 16 of the Drugs & Cosmetics Act, 1940, is in

violation of the citizen's right to life enshrined in Article 21 of the Constitution and also in violation of the directions given by this Hon'ble Court in *Vincent Panikurlangara*v. *Union of India* AIR 1987 990;

(B) That the failure of Respondent No. 1 to conduct a detailed investigation into the illegal drug approvals granted by Respondent No. 2 into approvals of Aceclofenac with Dotraverine, Buclizine, Letrozole, Deanxit, placenta and nimensulide for children is in violation of Respondent No. 1's written commitment to the Department Related Parliamentary Standing Committee on Health & Family Welfare and also in violation of the recommendation of the Expert Committee setup by Respondent No. 1. Such a failure to investigate these companies and recover the profits made by them also violates the citizen's fundamental right to life under Article 21 of the Constitution and isalso in violation of the directions given by this Hon'ble Court in *Vincent Panikurlangara*v. *Union of India* AIR 1987 990 as the failure to penalise such illegal approvals only encourages the private industry to repeat such mistakes at the cost of human life;

(C) That the failure of Respondent No. 1 to conduct a detailed investigation into the controversial files is a failure to adhere to the guidelines laid downin the judgment of the Hon'ble Delhi High Court in the case of *Union Of India* vs. *VishwasBhamburkar*[2013(297)ELT500(Del.)] and by the Hon'ble Central Information Commission in the case of *Om*

Prakash v. *Land & Building Dep. GNCTD, Delhi* (CIC/DS/A/2013/001788SA). The Hon'ble High Court had made it clear that departmental action was required to be taken against the person responsible for the missing files while the Hon'ble CIC had directed prosecution of the officers in question under the provisions of the Public Records Act, 1993. A failure to implement such binding directions from judicial bodies indicates an arbitrary action by Respondent No. 1, which action is in violation of the reasonableness requirement of Article 14 of the Constitution;;

(D) That the Report of the Expert Committee commissioned by Respondent No. 1 to suggest qualification criteria for senior level posts at Respondent No. 2suffers from a fundamental conflict of interest since the committee had as members former DCGIs who have an interest in maintaining status quo. The constitution of the committee was therefore arbitrary and unreasonable and therefore in violation of Article 14 of the Constitution;

(E) That Respondent No. 1 has failed to implement the recommendations of the Katoch Committee Report to conduct a series of studies/performance audits on the functioning of Respondent No. 2 and that such failure is violation of the citizen's fundamental right to life under Article 21 of the Constitution and also in violation of the directions given by this Hon'ble Court in *Vincent*

Panikurlangara v. *Union of India* AIR 1987 990,as the current structure of regulation does little to curb the increasing number of NSQ drugs in the Indian market;

(F) That the failure of Respondent No. 1 & Respondent No. 2 to create a nationwide database of NSQ drugs for a period of at least 5 years, isin violation of the citizen's fundamental right to know under Article 19(1)(a) of the Constitution as interpreted by the Supreme Court in several judgments;

(G) That the failure of Respondent No. 3 to make available online, the Register of Prosecutions & Register of NSQ of all its members is in violation of the citizen's fundamental 'right to know' under Article 19(1)(a) of the Constitution as interpreted by the Supreme Court in several judgments;;

(H) That the failure of Respondent No. 1 and Respondent No. 2 to conclude an investigation into the manufacturing plants of Ranbaxy (now owned by Sun Pharmaceuticals) is in violation of: *firstly* the commitment given by Respondent No. 1 in Parliament, *secondly* the citizen's fundamental right to life under Article 21 of the Constitution and *thirdly* also in violation of the directions given by this Hon'ble Court in *Vincent Panikurlangara* v. *Union of India* AIR 1987 990 since these manufacturing plants are most likely still supplying questionable drugs to the Indian market;

(I) That the failure of Respondent No. 2 to implement its circular no. DCG(I)/MISC/2013(87) dated June 26, 2013 and to conduct investigations into cases where foreign

regulators have issued adverse reports against Indian pharmaceutical companies violates *firstly* the citizen's fundamental right to life under Article 21 of the Constitution and *secondly* also violates the directions given by this Hon'ble Court in *Vincent Panikurlangara* v. *Union of India* AIR 1987 990since these manufacturing plants banned from supplying to the foreign market continue to supply to the Indian market;

(J) That the failure by Respondent No. 1 to enforce the recommendation of the Dr.Ranjit Roy Choudhary Committee Report to make it mandatory for all generic drug manufacturers to conduct bioequivalence studies (regardless of its 'new drug' status) is in gross violation of *firstly* the citizen's fundamental right to life under Article 21 of the Constitution and *secondly* also violates the directions given by this Hon'ble Court in *Vincent Panikurlangara* v. *Union of India* AIR 1987 990 since the lack of such studies affects the potency and safety of all generic drugs manufactured in India;

(I) That the failure of Respondent No. 1 to amend the Drugs & Cosmetics Rules, 1945 to implement Respondent No. 3's recommendation to make stability studies a mandatory requirements for all generic drug manufacturers is in gross violation of *firstly* the citizen's fundamental right to life under Article 21 of the Constitution and *secondly* also violates the directions given by this Hon'ble Court in *Vincent*

Panikurlangara v. *Union of India* AIR 1987 990 since the lack of such studies affects the potency and safety of all generic drugs manufactured in India;

(J) That the "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008" are *ultra vires* the provisions of the Drugs & Cosmetics Act and therefore arbitrary, unreasonable and in violation of Article 14 of the Constitution of India since these guidelines deviate from the quality norms laid down in Section 16 of the Drugs & Cosmetics Act, 1940. It may also be noted such deviations from the statutory scheme are in violation of judicial precedents rendered in the context of the Prevention of Food and Adulteration Act, 1954 by the Hon'ble Supreme Court in the case of *Jagdish Prasad* v. *State of West Bengal* (1972) 1 SCC 326 and the Hon'ble Kerala High Court in the case of *State of Kerala* v. *Vasudevan Nair* (1974 KLT 617 (FB). In both cases the Hon'ble Courts have made it amply clear that the standards laid down in the statute have to be followed strictly especially when human safety is at stake. By prescribing prosecution only in certain circumstances the Guidelines in effect alter the quality standards prescribed under the law;

(K) That the "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the

light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008" does not stand the test of reasonableness enshrined in Article 14 of the Constitution. In particular, the Guidelines create a classification based on the defect contained in the drug, rather than on the basis of the effect that the drug has on human beings. Thus a drug classified as having a Category B defect due to a dissolution failure or disintegration failure can be as dangerous as a spurious drug since it will not even dissolve in the bloodstream. There is no rational basis for recommending vigorous prosecutions only in cases of Category A drugs and not in Category B & C drugs when the effects of Category B & C drugs can be equally harmful to the human body;

(L) That the "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008" are *ultra vires* the provisions of the Drugs & Cosmetics Act since it instructs the Drug Inspectors to assess the intent of the accused even when the Drugs & Cosmetics Act is quite clear on the point that all offences under the Act are strict liability offences not requiring any assessment of criminal intent. From cases such as *Andhra Pradesh Grain and Seed Merchants Association etc.* v. *Union of India* (AIR 1971 SC 2346) it is crystal clear that such strict liability offences are constitutional and required to be strictly followed especially when human safety is at stake. The failure to implement such strict liability provisions leads to gross violation of *firstly* the citizen's fundamental right to life under Article 21 of the Constitution and *secondly*

also violates the directions given by this Hon'ble Court in *Vincent Panikurlangara* v. *Union of India* AIR 1987 990 since the lack of such studies affects the potency and safety of all generic drugs manufactured in India;

(M) That the current practice whereby different SLAs are suspending licences for different duration of time under the administrative penalties clause of Rules 85-I, for the manufacture of NSQ drugs is in violation of the equal protection clause under Article 14 because different authorities created under the same legislation cannot penalise the same deviations with different punishments in different states of the same country. All SLAs are required to be uniform and consistent in their approach under Rule 85-I;

(N) That the large scale differences in prosecutions by different drug inspectors, in different states, is leading to an inconsistent application of the Drugs & Cosmetics Act and the same is in gross violation of the equal protection clause under Article 14 because different authorities created under the same legislation cannot prosecute the same offences in a different manner in different states of the same country. All SLAs are required to be uniform and consistent in their approach to prosecutions.;

(O)That the failure of Session Judges across the country to award the mandatory minimum imprisonments prescribed in Section 27(d) of the Drugs & Cosmetics Act for the manufacture and sale of NSQ drugs on the basis of the marital status or family status of the accused is in violation of the law laid down in cases such as *State of Rajasthan* v. *Vinod Kumar* AIR2012SC2301 where the Hon'ble Supreme Court has clearly held that the proviso to mandatory minimum provisions should not be misused to grant a reprieve in every case;

(P) That various public procurement programs of drugs under the CGHS, Indian Railways and the Armed Forces Medical Services Depot are facing recurrent problems with the constant procurement of NSQ drugs thereby violating the public servant's fundamental right to life under Article 21 of the Constitution since it is very likely that large portion of public servants in India are consuming NSQ or subs-standard drugs;

PRAYER

On the basis of the aforementioned grounds, the Petitioner humbly prays for the following reliefs from this Hon'ble Court:-

(a) To issue a writ of mandamus directing the Respondent No.1, Union of India to frame binding guidelines for the recall of drugs which are not of standard quality, adulterated, spurious or misbranded;

(b) To issue an order directing the Respondent No.1 to set up a Committee, to be called the Drug Approvals Review Committee, for the purpose of examining any criminality in the manner in which faulty drug approvals were granted by the DCGI as discussed in paragraphs 30 to 46 of this petition and also for the purpose of examining whether the pharmaceutical companies in question can be ordered, under the principles of equity, to disgorge profits made through such illegal sales;

(c) To issue a writ of mandamus to the Respondent No.4 to conduct an audit of the file storage and archiving practices

of the Respondent No. 2 and to determine the number of missing files;

(d) To issue a writ of mandamus directing Respondent No. 2 to conduct an internal enquiry into the three missing files pertaining to controversial drugs, namely pefloxacin, lomefloxacin & sparfloxacin;

(e) To issue an order directing the Respondent No.1 to set up a Commission, consisting of 2 medical doctors nominated by Director AIIMs and 2 international public health experts to re-examine the issue of the appropriate qualification for persons who can head Respondent No.2;

(f) To issue a writ of mandamus to the Respondent No.4 to conduct a performance audit of Respondent No. 2 on the lines recommended by the Katoch Committee Report;

(g)To issue a writ of mandamus directing Respondent No. 1 to create a national, free, publically accessible digital database of all drug samples which have failed testing in all Central Government and State Government Laboratories over the last 5 years;

(h) To issue a writ of mandamus directing Respondent No. 3 to ensure that Registers of NSQ Drugs and Registers of Prosecution maintained by its members are proactively disclosed on the website of each member as per the requirements of Section 4 of the RTI Act;

(i) To issue a writ of mandamus directing Respondent No. 1 to submit an interim report on the status of the investigation

into the Ranbaxy scandal as ordered by the Government of India on 11th June, 2013;

(j) To issue a writ of mandamus to Respondent No. 1 to submit a status report on action/investigation taken by Respondent No. 2 into the Good Manufacturing Practices ("GMPs in short") of those Indian based pharmaceutical companies which have been banned, by foreign countries, from exporting to the domestic territories of these foreign countries;

(k) To issue a writ of mandamus to Respondent No. 3 to make mandatory bioequivalence studies from a public safety perspective, prior to granting licenses for manufacture of generic drugs;

(l) To issue a writ of mandamus to Respondent 1 to implement the recommendation of Respondent No. 3 in its 46th Report to make stability studies compulsory for all generic drugs manufactured in India;

(m) To issue a writ in the nature of certiorari for quashing the "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008" as ultra vires the Drugs & Cosmetics Act and the Constitution of India;

(n) To issue an order directing the Respondent No.1 to set up a Committee, consisting of a Senior Advocate of this Court, two retired drug inspectors of good standing and a retired Health Secretary to formulate uniform guidelines for

suspension and cancellation of licences under Rule 85-I of the Drugs and Cosmetics Rules, 1945", and to make recommendations regarding uniformity between different states on actions against licencees;

(o) To issue an order directing the Respondent No.1 to set up a Committee, consisting of a Senior Advocate of this Court, a retired Director of Public Prosecutions and a retired Drug Inspector to create a 'Manual on Investigations & Prosecutions under the Drugs & Cosmetics Act, 1940" so as to ensure uniformity of practices amongst all drug inspectors in all states;

(p) To issue sentencing guidelines under Section 27(d) of the Drugs & Cosmetics Act to guide Session Judges on the issue mandatory minimum punishment under Chapter IV of the D&C Act, 1940;

(q) To issue an order directing the Respondent No.1 to set up a Committee consisting of a nominee of Respondent No.4, a nominee of Respondent No. 1, a nominee of Secretary, Ministry of Finance to prepare uniform guidelines for blacklisting of suppliers who are found to be selling NSQ drugs to any arm of the government and to create a single database of all suppliers who have sold NSQ drugs to any public authority in the country;

(r) To direct the Respondent No.1 to make a reference to the Law Commission to consider the question of whether

India requires a new legislation to regulate the pharmaceutical industry;

(s) To pass any other order or direction that this Hon'ble Court deems fit in the interests of justice, equity and good conscience;

DRAWN BY:

PRASHANT REDDY T.
ADVOCATE

FILED BY:

ANITHA SHENOY
ADVOCATE FOR PETITIONER
ADVOCATE ON RECORD

Place: New Delhi
Draw on: 21.01.2016
Filed on: 24.01.2016

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL JURISDICTION)

WRIT PETITION (CIVIL) NO. OF 2016

IN THE MATTER OF: -

Dinesh S. Thakur ….. PETITIONER

VERSUS

Union of India & Ors. ….. RESPONDENTS

I.A. No. Of 2016: Application for exemption from disclosing PAN Number details

PAPER – BOOK

{FOR INDEX KINDLY SEE INSIDE}

ADVOCATES FOR THE PETITIONER: MS. ANITHA SHENOY

INDEX

S.NO	PARTICULARS	PAGES
1.	Listing Proforma	A1-A2
2.	Synopsis and List of Dates	B - L
3.	Writ Petition with Affidavit	1-85
4.	**Appendix** 1. Under Article 32 of the Constitution of India 2. Section 4 of the Right to Information Act, 2005 3. The Drugs and Cosmetics (Amendment) Act, 2008. 4. Under Section 85-I of Drugs and Cosmetics Rules, 1945 5. Under Section 27 (d) of the Drugs and Cosmetics Act, 1940 6. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties Under the Drugs and Cosmetics (Amendment) Act, 2008.	87-
5.	**ANNEXURE P-1** A true and correct copy of the Report of the Expert Committee headed by Dr. V.M. Katoch dated 20.11.2012.	
6.	**ANNEXURE P-2** A true and correct copy of the Order passed by the Government of India directing investigation into Good Manufacturing Practice compliance of Manufacturing facilities of Ranbaxy dated 11.06.2013.	

7. **ANNEXURE P-3**

A true and correct copy of the Report of the 46th meeting of the Drugs Consultative Committee dated 12 & 13 November, 2013.

8. **ANNEXURE P-4**

A true and correct copy of the letter sent by the Petitioner to the Union Health Minister with the representation dated 19.10.2014.

9. Letter seeking exemption from disclosing PAN details of the Petitioner.