

A report on fixing India's broken drug regulatory framework

By,

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About the Authors

Dinesh Thakur 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. who were involved in widespread data falsification in order to secure marketing approvals for its products. 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. The United States government simultaneously initiated civil & criminal proceedings against Ranbaxy on the basis of information submitted by him. 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. In recognition of his role in uncovering criminal behaviour at Ranbaxy, Dinesh has been 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 and Taxpayer Against Fraud (TAF's) Whistle blower of the Year.

More recently, he has been focussed on improving the regulatory framework governing development and manufacture of drugs in India. He filed a Public Interest Litigation in the Supreme Court of India based on extensive research and responses from the administration to over 125 Right to Information applications demonstrating dysfunction, apathy and gross mismanagement in the implementation of the regulatory framework governing drugs in India. Although the Supreme Court refused to hear his plea, he continues his research in this area with an intent to make fundamental changes to the regulatory framework to ensure safe and effective medicines for people of India.

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Table of Contents

Executive Summary	5
Introduction	10
Part I – The fragmented federal drug regulatory framework	14
Section A – The creation & evolution of the Drugs & Cosmetics Act, 1940.....	14
Section B: The post-independence reform aimed at consolidating drug regulation in India	17
Section C: The problems posed by the present federal drug regulatory framework	21
Section D: Is the sub-delegation of powers by the Central Government to the State Governments constitutional?	24
Section E: The recommendation of the Mashelkar Committee to centralise drug licensing.....	32
Section F: The failed legislative attempts to consolidate drug licensing activity between 2007 & 2015.....	34
Section G: Is a legislative amendment required to centralize drug licensing activities in India?	39
Part II – The weak investigation & enforcement mechanism under the Drugs & Cosmetics Act, 1940.....	39
Section A - Sampling of drugs by Drug Inspectors and the flaws therein.....	41
Section B: The offences in the Drugs & Cosmetics Act and the circumvention of these offences through the DCC guidelines;	46
Section C: The often flawed investigation & prosecution process followed by Drug Inspectors	53
Section E: Confusion in different states regarding courts with appropriate jurisdiction to prosecute offences under the Drugs & Cosmetics Act, 1940	74
Section F: The lack of enforcement of minimum mandatory prison sentences by the judiciary;	76
Section G: The suspension and cancellation of manufacturing licences.....	79
Part III – The absence of fundamental quality testing and recall norms in Indian law	82
Section A: The lack of mandatory bioequivalence testing under the Drugs & Cosmetics Rules & its consequences for public health;.....	83
Section B: The lack of mandatory stability testing under the Drugs & Cosmetics Rules.....	87
Section C: The lack of a mandatory recall mechanism in Indian law;	88

Part IV – The 59 th Report of the Parliamentary Standing Committee on Health & Family Welfare on the functioning of the CDSCO	93
Section A: Collusion and possible corruption in drug approvals	94
Section B: Missing files at the CDSCO	106
Section C: The unimplemented recommendations of the Katoch Committee Report	108
Section D: The qualification criteria for the post of the Drug Controller General of India (DCGI).....	110
Section E: The missing NSQ database.....	114
Part V – Sub-standard drugs in the public procurement system	117
Section A: The CAG Reports auditing the CGHS, AFMSD & the Indian Railways ...	118
Section B: The variance in black listing norms followed by the CGHS, AFMSD & the Indian Railways.....	121
C. The need for a public procurement law to specifically regulate procurement of medicine	122

Executive Summary

This report on the drug regulatory framework in India is based on extensive research undertaken by the authors. The main source for the data reported in this study are the responses from public authorities to requests for information filed by the authors under the Right to Information Act, 2005. Other important sources of data for this report are the official state reports by Parliamentary Committees, expert committees appointed by the Government of India and audit reports of the Comptroller & Auditor General (CAG). Based on this extensive research, the authors were able to identify various problems with the current drug regulatory framework. This executive summary provides a snapshot of the various issues raised in this report along with suggested solutions.

Part I - The fragmented federal drug regulatory framework

In this section of the report, we explain how the existence of 36 state licensing authorities in the country has led to a highly fragmented regulatory framework that presently governs the Indian pharmaceutical industry. This fragmented regulatory framework whereby a

manufacturer who get a license from one state authority can then sell its product across the country is at the root of the many problems with drug regulation in India. We examine this issue from a historical perspective in order to explain how Central Government had wanted to resolve this issue of multiple licensing authorities as far back as 1954, based on the recommendations of the Pharmaceutical Enquiry Committee, 1954. During the subsequent year, Parliament enacted the Drugs (Amendment) Act, 1955 transferring all licensing powers of the State Governments to the Central Government. Five years later, the Central Government inexplicably gave these powers back to the states through an amendment to the Drugs & Cosmetics Rules, 1945. We explain why such a sub-delegation of licensing powers to the State Governments is unconstitutional. This issue of centralising licensing of drug manufacture has been high on the government agenda over the last decade but the industry has opposed at least two legislative attempts which aimed at centralising licensing powers with a central authority. We conclude by pointing out that the Government can achieve these same results by merely amending the

existing Rule 69. A legislative amendment, while preferable, is not absolutely necessary at this stage.

Part II – The weak investigation & enforcement mechanism under the Drugs & Cosmetics Act, 1940

This section explains in significant detail, the manner in which the Drugs & Cosmetics Act is actually enforced on the ground. Since there was no available literature on this point, we filed multiple requests for information under the Right to Information Act, 2005 with the CDSCO, the Ministries of Health and various state authorities in Andhra Pradesh, Gujarat, Himachal Pradesh, Karnataka, Kerala, Uttarakhand, Tamil Nadu and Maharashtra. The process of obtaining cogent responses from the authorities has been very challenging. We received no responses, incomplete responses, redirection of our questions to different offices as the norm. However, based on the replies that we received, we have managed to construct a detailed portrait of just how weak the regulatory process is when it comes to investigation, prosecution and sentencing for offences related to Not of Standard Quality (NSQ) drugs. There are of course notable

exceptions like the drug regulator in Tamil Nadu but the picture emanating from most states is far from satisfactory.

The problems with the enforcement mechanism begin right from the time drug inspectors go to the market to draw samples for testing. Since the entire enforcement mechanism begins with this act of drawing samples, it is necessary for regulators to conduct the design this process based on sound statistical science and execute it transparently. However, our requests for information on the allocated budgets and the methodology of the sampling received vague answers from most states. With the exception of Tamil Nadu and Kerala, most states and the CDSCO were unable to give us any details on the budget for drawing samples. Similarly most states had no information on the methodology for collecting the samples – some inspectors were able to point to guidelines established by their departments but the guidelines were not based on rigorous statistical models. Even within states which had guidelines, not all the inspectors were aware of such guidelines. We conclude by recommending that the Ministry of Health enact rules under the Drugs & Cosmetics Act to implement a more scientific

methodology for drawing samples of drugs across all states.

Once the samples are tested in government laboratories and the test reports are returned to the drug inspector, all drugs which fail the drug testing are required to be investigated and prosecuted under the Drugs & Cosmetics Act. However, our research reveals only a very small percentage of these cases actually reach the stage of prosecution because of certain prosecution guidelines recommended by the Drugs Consultative Committee (DCC). These guidelines basically call on Drug Inspectors to ignore the binding quality standards recognised under Section 16 of the Act and instead follow the quality criteria recommended in the DCC guidelines while making a decision whether to criminally prosecute offences related to NSQ drugs. Some of the criteria in these guidelines are completely contrary to the Drugs & Cosmetics Act. For instance, under the Act, all offences related to quality are strict liability offences; i.e., the drug inspector is not required to prove the mental intent of the accused who may have been responsible for the manufacture of the NSQ drug. The guidelines however clearly require the drug inspector to ascertain the

criminal intent or gross negligence of the manufacturer before taking a decision to prosecute. We present a legal argument that these guidelines are illegal and unconstitutional because they go against the language and spirit of the Drugs & Cosmetics Act. From thereon, we explain how investigations are conducted in cases that are prosecuted and point to a litany of issues regarding the manner in which these investigations are carried out by drug inspectors, the problems faced by them and lastly, the problem with criminal courts who try such cases. As per the Drugs & Cosmetics Act, the offence of manufacturing a NSQ drug is punishable with a minimum prison term of one year; however, as we discovered, most judges, at least in the State of Karnataka sentence manufacturers with simple imprisonment till the rising of the court, which basically means that the person is let off once the judge rises for the day. Monetary fines are similarly miniscule. Even when drug inspectors opt for the option of cancellation or suspension of manufacturing licences, we noticed large scaled discrepancies between different states on the duration of such suspensions. There is also the issue of whether such suspensions are even enforceable over the long term.

Part III – The absence of fundamental quality testing and recall norms in Indian law

While the ability of the drug regulatory framework to detect and prosecute NSQ cases is highly questionable, a bigger issue which requires to be examined is whether Indian laws even provide for the kind of fundamental safety norms prescribed in developed foreign countries. From a quality perspective, we were quite shocked to learn that India currently does not require either bioequivalence studies or stability testing for most, not all, generics being sold in the Indian market. With regard to bioequivalence studies, the Dr. Ranjit Roy Choudhary Expert Committee had specifically recommended, in 2013, that such studies be made mandatory for **all** generics sold in the Indian market. However, the Drugs Consultative Committee (DCC) turned down this recommendation, while at the same time recommending that such testing be performed for exports to foreign countries in order to pre-empt any concerns regarding quality. Similarly, with regard to 'stability testing', which is a critical quality testing norm, the DCC itself recommended that the rules be amended to make such testing mandatory but the

government has failed to carry out such amendments. Last, but not least, is the fact that India does not have a nationwide drug recall system. There is basically no mechanism to ensure a nationwide withdrawal of a bad batch of drug once it is established that it fails a quality test in a particular state. We consider this to be a most serious lacuna in the regulatory framework.

Part IV – The 59th Report & 66th Report of the Parliamentary Standing Committee on Health & Family Welfare on the functioning of the CDSCO

In this part of our report, we examine the follow up action taken by the government in response to the scathing reports of the Parliamentary Standing Committee on the functioning of the CDSCO. In its 59th Report (2012) and 66th Report (2013), the Standing Committee on Health & Family Welfare had pointed to illegal drug approvals, missing files and other illegalities. Through RTI applications, we determined that despite giving written commitments on the issue of investigating illegal drug approvals the Ministry never carried out any follow-up action. Similarly, we discovered that the issue of missing files were never investigated as required under the Public

Records Act, 1993. We also found that the Ministry of Health has not yet commissioned the studies recommended by its own expert committee headed by Dr. Katoch to examine the functioning of the CDSCO. The two other important issues discussed in this part of the report pertain to the qualification criteria for the post of the DCGI and lastly the absence of a national database on NSQ drugs – both issues were raised in the 59th report.

Part V – Sub-standard drugs in the public procurement system

In this section of the report we discuss the issue of sub-standard drugs that have found their way through public procurement systems for public funded hospitals run by the Central Government, the Armed Forces and the Indian Railways. The Comptroller and Auditor General (CAG) has repeatedly highlighted the problem of sub-standard drugs in all these programs. We examine these various reports and investigated further by studying the blacklisting policies of three different public agencies. We propose that the government enact a public procurement law to govern the procurement of drugs by public funded organisations so as to foster more uniform

blacklisting norms and better information sharing between different agencies procuring medicine.

Introduction

The issues of quality and the efficacy of Indian manufactured medicines and the effectiveness of the Indian drug regulatory framework and its administration have come under increasing scrutiny over the last few years. The fact that foreign regulators have found a raft of issues with tens of pharmaceutical manufacturers in India while the Indian regulator, CDSCO has only issued public threats to take similar action against erring manufacturers has reinforced the narrative from the 59th Parliamentary Standing Committee Report which spoke of lack of competence and collusion between the regulator and the industry it regulates. Unfortunately, due to the lack of transparency in the workings of our regulatory processes, the public debate that has ensued in the media is short of nuance and detail that would inform the general public of the exact shortcomings of the drug regulatory system in India and its consequences.

Over the course of the last two years, we've conducted extensive research into the working of the Indian drug regulatory system. This report has been written with the intention of sharing the details of our research with the general public and we

hope it serves to educate the key stakeholders on the various shortcomings of the Indian drug regulatory framework along with proposals to reform the present scenario. The key focus of our research is to investigate the issue of sub-standard or NSQ drugs, rather than the problem of spurious or counterfeit drugs. It is important to understand the distinction between both substandard and spurious drugs. 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.

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;

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. Our study attempts to unpack and explain some of the legal issues surrounding the issue of NSQ drugs in India.

The report is divided into 5 parts:

Part I – The fragmented federal drug regulatory framework

1. The structure of the federal drug regulatory framework in India
2. The problems posed by the present federal drug regulatory framework
3. Whether the federal drug regulatory framework constitutional?
4. The failed legislative effort to amend the law

Part II – The weak investigation & enforcement mechanism under the Drugs & Cosmetics Act, 1940

1. Sampling of drugs by Drug Inspectors and the flaws therein
2. The offences in the Drugs & Cosmetics Act and the circumvention of these offences through the DCC guidelines
3. The often flawed investigation & prosecution process followed by Drug Inspectors
4. A summary of the problems faced in the investigations under the Drugs & Cosmetics Act: co-ordination, investigation tactics, GMP compliance
5. Confusion in different states regarding courts with appropriate jurisdiction to prosecute offences under the Drugs & Cosmetics Act, 1940

6. The lack of enforcement of minimum mandatory prison sentences by the judiciary
7. The suspension and cancellation of manufacturing licences

2. Differing blacklisting norms followed by different public procurement agencies
3. The need for a public procurement law to specifically regulate procurement of medicine

Part III – The absence of fundamental quality testing and recall norms in Indian law

1. The lack of mandatory bioequivalence testing under the Drugs & Cosmetics Rules
2. The lack of mandatory stability testing under the Drugs & Cosmetics Rules
3. The lack of a mandatory recall mechanism in Indian law

Part IV – The 59th Report & 66th Report of the Parliamentary Standing Committee on Health & Family Welfare on the functioning of the CDSCO

1. Corruption in the drug approval process
2. Missing documents to fix accountability
3. The Katoch Committee Report
4. The qualification criteria for the post of the Drug Controller General of India (DCGI)
5. The missing NSQ database

Part V – Sub-standard drugs in the public procurement system

1. The CAG reports on the CGHS, AFMSD and the Indian Railways

Part I – The fragmented federal drug regulatory framework

Section A – The creation & evolution of the Drugs & Cosmetics Act, 1940

1. The very first public call for the enactment of a new drug regulatory law in India can be traced to a resolution moved by the Hon'ble Sir Haroon Jaffer on the 9th of March, 1927 before the Council of State, "recommending to the Governor-General in Council to take immediate measures to control the craze for medicinal drugs by legislation for standardization of the preparation and sale of such drugs".¹ The Council of States eventually adopted a resolution, urging all provincial governments (state governments) to take steps as necessary to control the indiscriminate use of medicinal drugs and to legislate for the standardization and sale of such drugs.² In the Legislative Assembly, Lieut. Col. H.A.J. Gidney made reference to the "gigantic quinine fraud" and requested for the enactment of a Food & Drugs Act and a Pharmacy and

Poisons Act to stop India from becoming a dumping ground for adulterated and quack medicines from across the world.³

2. The concerns in the legislature coincided with calls for greater regulation from both the scientific community and the press. Around the same time, the Government of India, in consultation with the provincial governments issued a resolution on 11th August, 1930 appointing a committee, called the Drugs Enquiry Committee, with a mandate to: (i) Enquire into the extent to which sub-standard and adulterated drugs were being imported into British-India and make recommendation on the requirement to control such imports; (ii) Whether the recommendations for imports could apply to even indigenously manufactured drugs; & (iii) To enquire into the necessity of legislation to restrict the profession of pharmacy.⁴
3. After holding extensive consultations with the medical community, the pharmaceutical industry and other

¹ Report of the Drugs Enquiry Committee (1930-31) at p.1.

² *Id.*

³ Page 2

⁴ *Id.*

stakeholders and conducting a detailed review of drug regulation in other countries, the Committee submitted a 174 page report to the Government of India on 29th March, 1931.⁵

4. Regarding the need for legislation to regulate the drug industry, the Committee recommended that “there should be legislation to control drugs” and that “legislation should be central with a view to secure effectiveness and uniformity in control throughout India.”⁶ Although the Committee proposed a Central Legislation, it restricted the role of the institutions under the Central Government to setting standards. The task of enforcing these different standards was left largely to the provincial governments. However, one potential roadblock at the time was whether the Indian Legislature at the centre would have the powers to legislate on a uniform legislation for the entire country. This was an issue because the Devolution Rules under Section 45-A of the Government of India Act distributed legislative powers between the Indian

Legislature and the various provincial assemblies. The subjects of medical administration, public health, adulteration of articles, control of poisons, development of industries etc. were under provincial purview. The Committee however argued that a Central legislation was still possible because the Government of India, Act allowed the Indian legislature to legislate on provincial subjects with the prior sanction of the Governor General.

5. On the basis of recommendations by the Drugs Enquiry Committee, a Bill was introduced in 1937 in the Central Legislative Assembly to regulate the import of drugs into British India. The Bill was referred to a Select Committee which recommended a more comprehensive bill to regulate even the domestic manufacture and distribution of drugs. In order to widen the ambit of the legislation, the Government of India wrote to the provincial governments to request their respective provincial assemblies “to pass resolutions under Section 103 of the Government of India Act, 1935

⁵ *Ibid* at Page 159.

⁶ *Ibid* at page 158.

empowering the Central Legislature to pass an Act for regulating such matters relating to the control of drugs as fall within the Provincial Legislative List" in the Seventh Schedule to the Government of India Act, 1935. Once the various provincial assemblies passed such resolutions, the Government of India introduced a Bill in the Indian Legislature which was eventually enacted as the Drugs Act, 1940 (cosmetics were included within the ambit of the legislation and its title only in the year 1962).

6. Although enacted as a Central Legislation, the Drugs Act, 1940 split regulatory powers between the Centre & Provinces. The Act delegated substantial powers to both the Centre and the Provincial Governments to draft rules for the setting of standards for their respective areas of regulation i.e., import and domestic manufacture/sale, respectively. Section 33 as it existed in 1940 specifically delegated to the Provincial Governments the power to licences the manufacture of drugs and also the power to nominate the authority

empowered to issue such licences. The language of Section 33 as it existed in 1940 is reproduced as follows:

Section 33 (1) The Provincial Government may, after consultation with the Board and after previous publication by notification in the official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.

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

(e) prescribe the forms of licences for the manufacture for sale, for the sale and for the distribution of drugs or any specified drug or class of drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

On the basis of this provision, various provinces in British India, notified their own set of rules such as the Bombay Drug Rules, 1946; West Bengal Drug Rules, 1946 & the Madras Drug Rules, 1945 etc.

Section B: The post-independence reform aimed at consolidating drug regulation in India

7. The first post-independence amendments to the Drugs Act, 1940 took place when Parliament enacted the Drugs (Amendment) Act, 1955. This legislation made an important change to the scheme of the Drugs & Cosmetics Act, 1940 by transferring to the Central Government, the powers under the original Section 33 of the Drugs Act, 1940. As explained earlier, the originally enacted Section 33 in 1940 delegated substantial powers to the erstwhile provincial governments (now called the state governments) to formulate rules for all the provisions under Chapter IV of the legislation which dealt with 'manufacture, sale and distribution' of drugs. The amendments in 1955 altered the language of the erstwhile Section 33 to read as follows:

*Section 33 (1) The **Central** Government may, after consultation with the Board and after previous publication by notification in the official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:*

It should be noted that there was no amendment to the existing sub-Section 33(2) (e) but since the title of the section was itself altered, all the existing powers of the State Government were now transferred to the Central Government.

8. With this amendment, the Central Government was given substantial responsibility for regulating the domestic manufacture of drugs. Until these amendments, the Central Government had the responsibility of regulating just imports.
9. It is important to understand the legislative intent behind these amendments. The "Statement of Objects & Reasons" (a legitimate aid to statutory interpretation), to the Drugs Bill, 1954 explains one of the motivations for the amendments as follows:

It has further been found necessary that with a view to maintaining uniformity throughout the States the power to make rules under Chapter IV with respect to the manufacture, sale and distribution of drugs, which is at present vested in the State

Governments should be entrusted to the Central Government.

10. Similarly the Minister's statement in Parliament during Parliamentary debates can be used as an aid to interpreting a statute. During the discussion in the Rajya Sabha the Minister of Health while introducing the Bill on 31 August, 1954 told the Council that:

And there was need also, in the present circumstances, for the assumption by the Central Government of rule-making powers, which up till now had been in the hands of the States, in order to have a uniform policy.

11. During the discussion in the Lok Sabha on February 28, 1955 the Minister made a similar statement saying:

One of the main amendments is the assumption by the Central Government of rule-making powers under chapter IV. I may say that the States are absolutely in agreement with us on this. Many of the important drugs in the country are imported and because they enter into inter-state

commerce, it is essential that the rules governing their standards should be uniform throughout India.

12. It is also important to note the recommendations made in the Report of The Pharmaceutical Enquiry Committee in 1954 which is the same year in which the Drugs (Amendment) Bill, 1954 was introduced in Parliament. In pertinent part, the Committee had argued for a central regulator on the following grounds:

In very many States, the Drugs Act is so poorly administered that we found that factories, which had been licensed were located in insanitary places and their premises maintained in no better conditions. They also had no proper equipment for manufacture or testing and neither the manufacturers nor the State were exercising any control on the quality of the products made by them. The products of these factories were a menace not only to the particular State, in which they were located, but also to the neighbouring States, to whose market they found their way. The people of the neighbouring States were in no way benefitted in spite of

the fact that the Act was being administered there in a better manner. When these points were brought to the notice of the State Drugs Controllers, they appeared to be helpless in the matter, either because they were afraid that by closing down such factories, it might lead to employment, labour unrest etc., or they had their own misgivings of the powers delegated to them under the Drugs Act to take such steps. It is, therefore necessary to centralise the administration of the Drugs Act to bring about a uniform implementation of the Drugs Act throughout the country for proper co-ordination with the working of the Industries (Development & Regulation) Act to be possible.

13. The above extracts from the Parliamentary record and government's own expert committee report, gives the historical context of the Drugs (Amendment) Bill, 1954 which eventually got enacted into law as the Drugs (Amendment) Act, 1955. It is quite clear thus that the legislative intent at the time was aimed at centralizing certain aspects of drug regulation such as rule-making and

licensing of manufacturing units because of the difficulties posed by multiple licensing authorities in different states.

14. This was the understanding even in 1960, when the government introduced the Drugs (Amendment) Bill, 1960. The "Statement of Objects & Reasons" to this Bill stated:

The Pharmaceutical Enquiry Committee appointed by the Government of India to make a comprehensive survey of the pharmaceutical industry, trade and profession in the country unanimously recommended that the Drugs Standard Control which was exercised by State Governments should be centralised for a better enforcement of the Drugs Act, 1940. On the basis of this recommendation of the Committee it is proposed to amend the Drugs Act, 1940 so as to empower the Central Government to control the manufacture of drugs, to appoint Inspectors for inspecting manufacturing premises and taking samples of drugs, to appoint Government Analysts to whom samples drawn by such Inspectors

could be sent for analysis and to issue directions to State Governments for carrying into execution any of the provisions of the Act.

(a) in the case of repacking of drugs for sale or distribution, in Form 24-B; and
(b) In any other case, in Form 24;

*Schedule C & C1 to the Drugs & Cosmetics Rules, 1945 basically cover all allopathic drugs.

15. However despite this stated intention of the centralising of licensing powers with the central regulator, the Government amended the rules in 1960 to give back licensing powers to the State Governments. Such amendments to the rules do not require prior approval of the Parliament and can be carried out by Central Government via a gazette notification. The existing Rule 69 in the Drug Rules, 1945 was amended to read as follows:

16. From the above amendment, it is obvious that despite the amendment to Section 33 being affected by Parliament with the aim of transferring erstwhile licensing powers of the State Governments to the Central Government, the subordinate legislation i.e., the Drug Rules, 1945 was amended by the Central Government, in 1960, to give licensing powers back to the State Governments. The reason for this divergence between the legislative mandate and governmental action is not known. As a result, India continues to have a fragmented regulatory framework with over 36 different licensing authorities across the length and breadth of the country.

69. *Application for licence to manufacture drugs other than those specified in Schedules C and C(1) to the Drug Rules.*-(1) *Application for the grant or renewal of licences to manufacture for sale of drugs other than those specified in Schedules C and C(1) shall be made to the licensing authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the licensing authority) and shall be made-*

Section C: The problems posed by the present federal drug regulatory framework

17. As a result of the amendment to Rule 69 of the Drugs & Cosmetics Rules, 1945, each and every state government and union territory administration has the power to issue licences to pharmaceutical manufacturers operating from within their respective jurisdiction. As a consequence, there are a total of 36 different State Licensing Authorities (SLAs) which are authorised to issue manufacturing licences for generic drugs. [However 'new drugs' as defined in Rule 122E of the Drugs & Cosmetics Rules, 1945 still require prior approval from the Central Licensing Authority (CLA) which is the DCGI.] Once a licence is issued in one state, the pharmaceutical drugs manufactured as a result of such a licence can, *de facto*, be then sold across the country in all states. If and when a drug manufactured in one state is detected to be Not-of-Standard Quality (NSQ) in a different state, the Drug Inspector in such state may initiate prosecution against the

licensee but will not have the power to suspend or cancel the manufacturing licence, or even inspect the manufacturing plant, as only the 'home' SLA (which issued the manufacturing licence) can cancel or suspend the licence, or inspect the manufacturing plant. In most cases, the Drug Inspector who has detected the NSQ sample will write to the SLA who has issued the licence informing them of the violations and requesting for action to be taken against the offending licensee.

18. Predictably, such a cumbersome legal framework with multiple regulators has led to poor co-ordination and often inconsistent application of law. A few of the consequences of having such multiple regulators are listed below:

19. **(i) Different standards of recruitment and training in each state leads to differing standards of enforcement of the law:** Currently, each state's drug control department conducts its own recruitment based on the qualification criteria laid down in the Drugs & Cosmetics Rules, 1945. Since the recruitment process is different for each state, the training process is also

most likely different since each state is responsible for its own drug inspectors. A natural result of such differences is that drug inspectors in different states enforce the provisions of the law differently. This conclusion is easily supported by a comparison of criminal complaints filed by drug inspectors of different states such as Tamil Nadu, Maharashtra and Andhra Pradesh for offences under the Drugs & Cosmetics Act, 1940. From a *prima facie* reading of the complaints it is obvious that the drug inspectors from Tamil Nadu are better trained in investigations than drug inspectors in most other states as their investigations are more thorough and rigorous. There is also a difference in how each state prosecutes offences under the Drugs & Cosmetics Act, 1940. For example, most states prosecute only the manufacturer of the NSQ drugs, while some states charge even the pharmacist selling such drugs. The interpretation of the Drugs & Cosmetics Act therefore varies from state to state.

20. **(ii) Poor inter-state co-ordination on the issue of drug recalls:** As per the law, Drug Inspectors in each state are

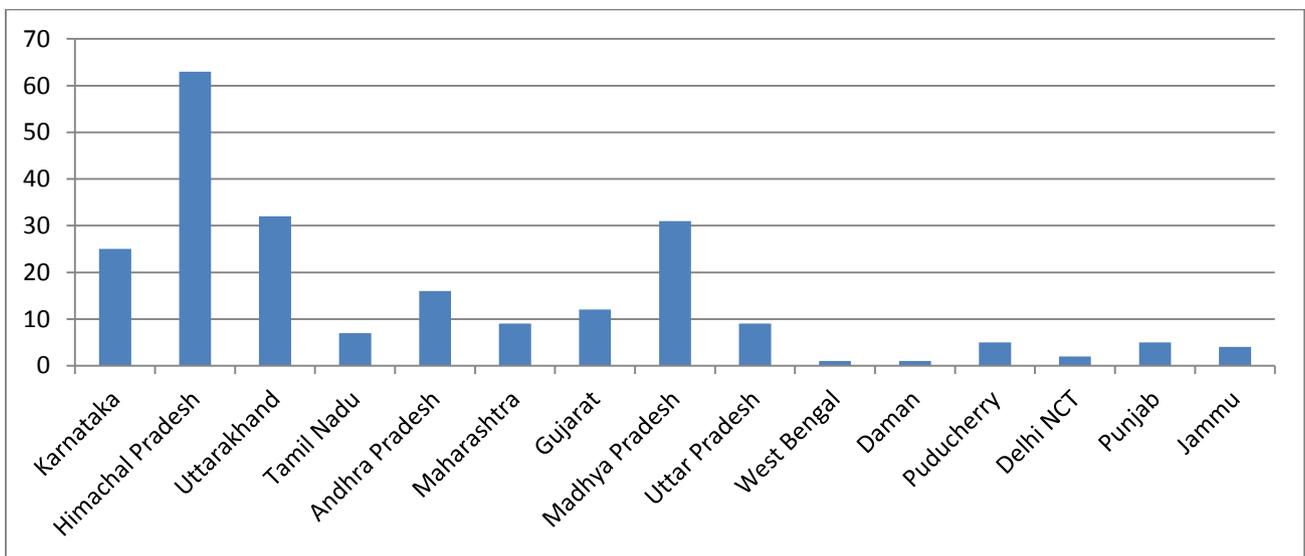
required to draw drug samples from the market for quality testing and if a sample fails such testing, the State Drugs Controller may order the manufacturer in question to withdraw the drug from the market. However such information is rarely shared with other state regulators as a result of which a NSQ batch withdrawn from one state can be sold in another state. 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 publicly voiced concerns that the drugs ordered to be recalled from one state were being sold in another state.

21. **(iii) Different states suspend licences under Rule 85-I for different durations:** An illustrative example of inconsistent administration of the law in different states is the significant difference in the duration for which each state suspends a manufacturing licence as punishment for manufacturing NSQ drugs. In order to establish this difference in the duration for which

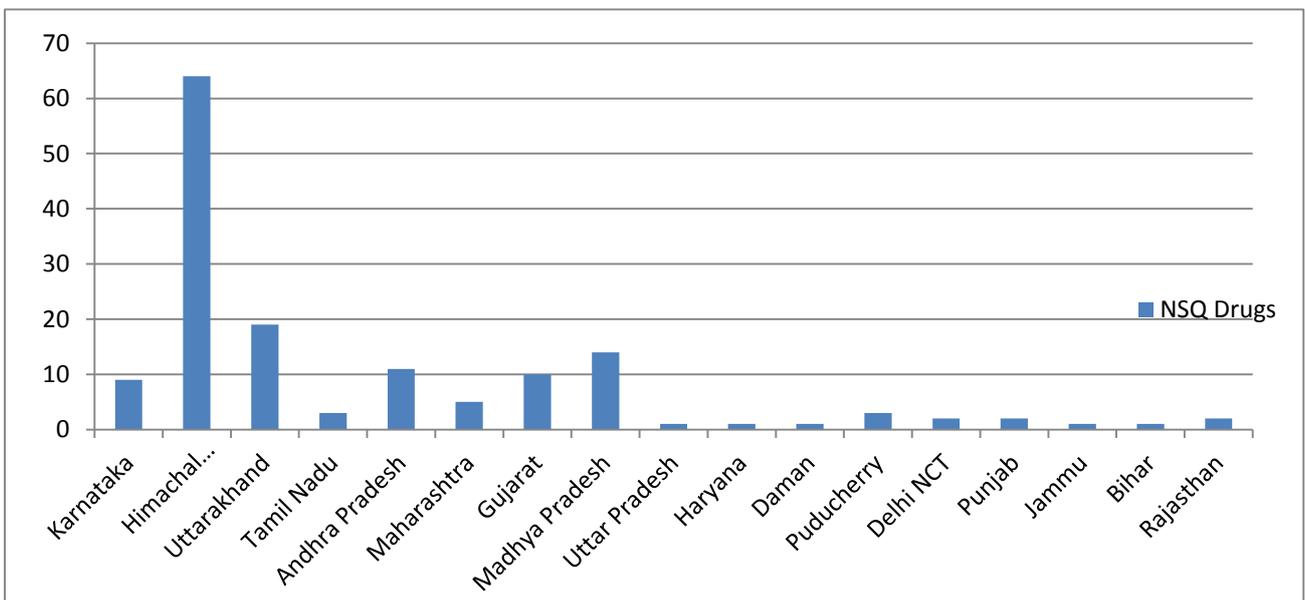
licences are suspended, we procured, under the RTI Act, copies of the Register of NSQ drugs maintained by the Karnataka Drugs Control Department (KDCD). This Register contains details of all the NSQ drugs

detected by the KDCD within the state of Karnataka and the action taken against them.

22. Below is a graphical representation of the states (i.e., the state which issued the manufacturing licence) from which the KDCD detected NSQ drugs in the year 2012-13.



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



24. 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, under the current law, 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 requesting that action be taken against the licensee. 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 a licence for just 1 day. This is one example of how the multiplicity of

licensing authorities is causing the inconsistent application of the law across the country.

Section D: Is the sub-delegation of powers by the Central Government to the State Governments constitutional?

25. The theory regarding delegation of powers is based on the constitutional theory of 'separation of powers' where the legislature makes the law, the executive executes the law and the judiciary resolves disputes regarding the interpretation of law. Such a separation of powers is meant to ensure a balance of powers by establishing checks and balances but it is almost impossible to maintain such a strict demarcation of powers in reality. As a result, it is inevitable that the executive will at times also resolve disputes and also make certain laws. The question is unto what extent the Executive can exercise its law making and judicial functions without disrupting the separation of powers doctrine.

26. Unlike some countries with written constitutions, the Indian Constitution does not clearly provide for a strict separation of powers between the legislature, the executive and the judiciary. However there has been an implicit acceptance of the 'separation of powers' doctrine through a series of judicial precedents starting right after independence in 1947. In the early days post-independence, a bench of seven judges of the erstwhile Federal Court was called upon to decide the limits of delegated legislation from the legislature to the executive in the case of *In Re Delhi Laws* (1951 AIR 332). While generally upholding the principle of delegated legislation, the Court made it clear that "essential legislative functions" could not be delegated by the legislature to the executive – this is generally understood as being the policy making function of the legislature.

27. Independent of the issue of the legislature delegating legislative powers to the executive, there is also the issue of how the executive exercises these delegated powers. Very often the executive authority to

whom power is delegated further sub-delegates such power to a subordinate authority. Whether or not sub-delegation is legal depends on the wording of the parliamentary legislation delegating the power to the executive authority in the first place. The oft quoted principle of statutory interpretation in this regard is the Latin maxim of *delegatus non potest delegare*, which means that a person to whom power has been delegated cannot further delegate that said power. The logic behind this maxim is simple: if the legislature has selected a certain authority for a certain task, it expects that authority to do the task. However, it should be noted that this is maxim is not construed strictly in cases where the legislation uses language allowing the executive authority to further sub-delegate its power. The controlling factor is therefore usually the language of the legislation.

28. At this stage it may be relevant to discuss certain Supreme Court precedents on the issue of sub-delegation:

(i) One of the first cases on the issue of sub-delegation is the case of *The Barium Chemicals Ltd. and Anr. v. The Company Law Board And Others* (1966 SCR 311). This case primarily involved questions of company law. One of the ancillary issues that came up in this case was whether certain powers delegated by the Central Government to the Company Law Board (CLB) could be exercised by only the Chairperson and not the entire Board. In specific, S. 237 of the Companies Act allowed the Central Government to delegate certain powers of investigation to the CLB. These powers were exercised by only the Chairperson of the CLB who ordered an investigation. The company challenged the exercise of these powers by the Chairperson on the grounds that the power was delegated to the entire Board and the Chairperson could not exercise such powers by himself. The CLB however justified such sub-delegation on the

grounds that Rules drafted by the Central Government under a different provision of the Companies Act, allowed the Chairperson to allocate the business of the CLB as he saw fit. On the issue of sub-delegation, three of the five judges ruled in favour of the CLB. Two of these three judges reasoned that “*sub-delegation can be sustained if permitted by an express provision or by necessary implication. Where, as here, what is sub-delegated is an administrative power and control over its exercise is retained by the nominee of Parliament, that is, here the Central Government, the power to make a delegation may be inferred*”. Two of the 5 judges dissented on this point. The test laid down by this case however appears to be that sub-delegation is permissible if it is made to an authority over which the delegating authority still has control.

(ii) In the case of *Sahni Silk Mills Pvt. Ltd. v. ESI Corp.* (1994 SCC (5) 346) the point of dispute was the scope of delegation under Section 94-A of the Employees State Insurance Act, 1948. This provision allowed the Employee State Insurance Corporation (ESIC) to delegate its powers and functions to any officer or

authority subordinate to the Corporation. In the exercise of these powers, the Corporation passed a resolution delegating the power to impose and recover damages to any officer or authority who was authorised by the Director General of the Corporation and who was subordinate to the Corporation. The sub-delegation in this case happened because the Corporation was exercising its powers to delegate functions to the director-general who could then further sub-delegate these powers to any officer or authority subordinate to the corporation. Multiple High Courts had ruled that such sub-delegation was impermissible and ESIC had appealed to the Supreme Court against these decisions. The Supreme Court however dismissed the appeal saying "According to us, Parliament while introducing Section 94-A in the Act, only conceived direct delegation by the Corporation to different officers or authorities, subordinate to the Corporation, and there is no scope for such delegate to sub-delegate that power, by authorising any other officer to exercise or perform the power so delegated." The Court reasoned

"From Section 94-A it does not appear that Parliament vested power in the Corporation to delegate its power on any officer or authority subordinate to the Corporation, and also vested power in the Corporation to empower such officer or authority, to authorise any other officer to exercise the said power under Section 85-B(1). If Section 94-A had a provision enabling the Corporation, not only to delegate its power to any other officer or authority subordinate to the Corporation, but also to empower such officer or authority in its own turn to authorise any other officer to exercise that power, the resolution could have been sustained...". Thus, in this case although the authority sub-delegating power, probably had control over the authority to whom power was being sub-delegated, the Court disallowed such sub-delegation because such sub-delegation was not clearly allowed for in the statute.

(iii) Another pertinent case on the issue of sub-delegation is the case of *A.K. Roy & Anr. v. State of Punjab* (1986 SCR (3) 961). In this case S. 20 of the Prevention of Food Adulteration, 1954 allows prosecutions to be instituted

either by the State Government or the Central Government or by a person authorized in this behalf by the State or Central Government. Rule 3 of the State Rules in Punjab delegated this power to the Food (Health) Authority of the State. This Food (Health) Authority further sub-delegated its powers to institute prosecutions to the Food Inspector, Faridkot. This sub-delegation was challenged and struck down by the Supreme Court. The Court held *“Where a power is given to do a certain thing in a certain way the thing must be done in that way or not at all. Other modes of performance are necessarily forbidden. The intention of the Legislature in enacting s. 20(1) was to confer power on the authority specified therein, which power had to be exercised in the manner provided and not otherwise.”*. The Court also held that *“It was open to the State Government to have issued a notification under s. 20(1) conferring authority on the Food Inspector to launch prosecutions for an offence under the Act, as is the practice in other States. The Food Inspector having been authorised by the Director of Health Service and not the*

State Government, he was not a person who had been authorised by any general or special order issued by the Central Government or the State Governments.”

29. The principle reiterated in all these cases by the Supreme Court is that sub-delegation may be permissible only if it is allowed by the governing parliamentary legislation. In both the *A.K. Roy* case and the *Sahni Silk* case, the Supreme Court was quite categorical in striking down certain executive notifications on the grounds that it constituted impermissible sub-delegation. The *Barium Chemicals* case is slightly more confusing as it appears to hint at sub-delegation being permissible in all cases where the authority delegating the power has the power to control the authority exercising the sub-delegated power. Therefore, in order to establish the vires or other of Rule 69 and its associated rules it is necessary to examine the wording of Section 33(2) (e) of the Act.

30. A literal interpretation of S.33 (2) (e):

The cardinal rule of statutory interpretation is to give the words of a statute a simple literal reading. On a simple reading of S. 33(2)(e), it is possible to make the following two arguments:

(a) The first argument is the use of a singular “authority” in S. 33(2) (e). The sentence specifically reads as follows: “*the authority empowered to issue the same*”. Literally interpreted, this means that Parliament wanted the Central Government to appoint only one authority to issue licences for all manufacturing activities. However Rule 69 states that the licensing authority shall be appointed by the State Government (which is defined in the legislation to include “Union Territories”). This has resulted in India having not 1 but 36 different regulators across the country which can license the manufacture of drugs. As a result it may be possible to argue that Rule 69 is ultra vires S. 33(2) (e) of the Act.

(b) The second argument that can be made on a literal interpretation of S. 33(2) (e) is the fact that the provision requires the Central Government to appoint the licensing authority by itself

– there is no mention in the provision that the Central Government may sub-delegate this power to the State Government as has been done in Rule 69 – which clearly states that the licensing authority will be appointed by the State Government. If the Act (i.e. S.33) requires the Central Government to appoint the licensing authority by itself it follows that the Central Government cannot delegate this power away via the Rules. Therefore it is possible to argue that Rule 69 is ultra vires S. 33(2) (e) of the Act because it illegally sub-delegates this power to the State Government. Even the limited sub-delegation made possible by the *Barium Chemicals* case is not possible in this case because the State Governments are not under the control of the Central Government.

31. A purposive interpretation of S. 33(2)

(e): Apart from a literal interpretation, it is also possible to interpret a provision by trying to discern the legislative intent behind a particular law or a particular amendment. In this particular case, it is necessary to ask why Parliament enacted the Drugs (Amendment) Act, 1955. The exhaustive and extensive

answer to this question has already been explained above. From the parliamentary debates, the government's own expert committee report and the "Statement of Objects & Reasons" accompanying the Bill, it is clear that the purpose of the amendments in 1955 was to centralize certain aspects of drug regulation in India, including the aspect of licensing of manufacturing. It is especially necessary to consider the "Statement of Objects & Reasons" which states "It has further been found necessary that with a view to maintaining uniformity throughout the States the power to make rules under Chapter IV with respect to the manufacture, sale and distribution of drugs, which is at present vested in the State Governments should be entrusted to the Central Government". *This makes it clear that Parliament wanted to shift all of the power in Chapter IV from the State Government to the Central Government so as to have uniformity across the country.* The fact that States were stripped off their ruling making powers makes it quite clear that Parliament could not have intended

for Central Government to vest these same powers back in the State Governments in Rule 69. Having licensing powers vested in every State Government across the country would almost never bring in uniformity in drug regulation as there would be no coordination and consistency of standards across different states. Since this was the problem sought to be resolved by the 1955 amendment, it is but obvious that Section 33(2) (e) sought to vest all licensing powers in a single licensing authority appointed by the Central Government rather than multiple licensing authorities appointed by respective state governments. To this extent it is possible to argue Rule 69 in its current form is *ultra vires* Section 33(2) (e).

32. In addition to the arguments above, it may also help to understand parliamentary intent by looking at other regulatory statutes where Parliament has expressly mentioned when it wanted State Governments included in the regulatory process. Illustratively, attention is drawn to the scheme of delegation followed in three different legislation of the same era as the 1955 Amendment to the

Drugs Act, two of which are regulatory laws similar to the Drugs & Cosmetics Act, 1940:

(a) Prevention of Food Adulteration Act, 1954: This is a legislation enacted by Parliament for the purpose of curbing food adulteration. This legislation again clearly demarcates powers between the Central Government and the State Government. In the legislation, Parliament directly delegates certain powers with the State Governments in Section 24, while other powers have been delegated to the Central Government in Section 23.

(b) Insecticide Act, 1968: This is a legislation enacted by Parliament for the purpose of regulating the manufacture, sale, transport, distribution and use of insecticides. The division of powers between the Central Government and State Government has been made very clearly in the text of the legislation itself, rather than the rule. In Section 12 & 13 of the legislation, Parliament clearly delegates power to the State Government to carry out the function

of licensing manufacture of insecticides.

(c) The Essential Commodities Act, 1955: This is a legislation enacted by Parliament to control the production, supply and distribution of the trade and commerce of certain commodities. In Section 5 of this legislation, Parliament has clearly delegated to the Central Government the right to sub-delegate certain powers to the State Governments. The manner in which these legislation have been drafted indicates that if the Parliament wanted to delegate certain powers to the State Government, it would have done so directly or would have expressly authorized the Central Government to do the same in the text of the statute.

33. In light of the above arguments above it is possible to convincingly argue that Rule 69 and its associated rules are ultra vires Section 33(2) (e) of the drugs & Cosmetics Act, 1940.

Section E: The recommendation of the Mashelkar Committee to centralise drug licensing

34. In 2003, the Government of India setup an expert committee under the Chairmanship of Dr. R. A. Mashelkar with a broad mandate to study and recommend steps to improve India's drug regulatory framework, including the growing problem of sub-standard or spurious drugs in the Indian market. From the outset, the composition of the committee was flawed because it included as its members, representatives of the pharmaceutical industry, senior bureaucrats from State Regulators and the Central Drug Regulator, all of whom had a vested interest in preserving the status quo. The choice of such members may have conflicted with the mandate of the committee in exposing the failures of drug regulation in India and recommend radical reforms.

35. It was therefore not surprising that the final report of the Committee did a rather poor job of analysing the problems with India's drug regulatory system or even properly understanding the manner in which India's regulatory

system evolved from its origins in the forties. However the committee did an adequate job of analysing the fact that state regulators across the country were neither uniform nor efficient in their implementation of the Drugs & Cosmetics Act, 1940. The Committee notes that a previous study by the National Human Rights Commission (NHRC) of drug regulation in India in the year 1999 had made similar observations; specifically: "the present dual system of control does not appear to have achieved desired effectiveness, therefore, Central Government must immediately take steps to examine the entire system of Licensing (including loan licensing), Certification and Complaint handling under effective Central Government control through CLAA or other suitable means".

36. As a solution to this problem of individual states administering licensing activities in a manner that was not consistent or uniform across the country, the Committee recommended the creation of a Central Drug Administration (CDA) which would be given the sole

mandate for licensing all manufacturing units across the country.⁷ It notes how this issue has been proposed by successive committees as far back as 1974 when the Hathi Committee had made a similar recommendation to create a national drug regulator. The Hathi Committee's recommendation was reiterated in the Drug Policy of 1986 and 1994 but was never implemented by the Government. In specific, para 33 of the Hathi committee report noted "quality control of products manufactured anywhere in India was not solely the responsibility of the state in which the manufacturing unit is located, since the product is sold all over the country. If a unit in one state was allowed to manufacture and market a product of substandard quality, this would nullify the measures taken by other states. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country".

37. If a centralized system of licensing had been implemented, it would have affected a major shift in the existing paradigm where licensing powers now exist with the State Governments. With a centralization of licensing powers, the state drug controllers would have lost a major source of revenue that they earn from licensing activities. As a result, the Mashelkar Committee does note that most state drug controllers appeared to oppose the move to consolidate drug regulation under a CDA. The Commissioner of the Food & Drug Administration, Government of Maharashtra who was on the Expert Committee filed a dissenting note voicing his disagreement with the majority opinion of the Committee.⁸

⁷ Report of the Expert Committee on 'A comprehensive examination of drug regulatory issues, including the

problem of spurious drugs', Ministry of Health & Family Welfare, Government of India (2003) at p.51

⁸ *Ibid* at p. 45

Section F: The failed legislative attempts to consolidate drug licensing activity between 2007 & 2015

38. After the submission of the Report of the Expert Committee in November 2003, the Government made three different legislative attempts to create a centralized drug regulatory administration on the lines recommended by the Expert Committee report submitted in November, 2003. Within a month of the report being submitted, the Government of India introduced the Drugs & Cosmetics (Amendment) Bill 2003 in the Lok Sabha.⁹ A copy of the bill is currently unavailable on known public databases. That Bill lapsed because of the dissolution of the Lok Sabha. Subsequently, the new government elected into office in 2004 introduced the Drugs & Cosmetics (Amendment) Bill 2005. Although the "Statement" of the Minister accompanying the Bill states that the government was aiming to implement the Expert Committee's recommendation, the fact of the

matter is that the Bill only proposed increasing punishment for the manufacture of spurious & adulterated drugs and did not propose the creation of a CDA, as recommended by the Expert Committee in 2003. That Bill was enacted into law by both Houses of Parliament in 2008 as the Drugs & Cosmetics (Amendment) Act, 2008.

39. In 2007, the Government of India introduced another bill – the Drugs & Cosmetics (Amendment) Bill 2007. In the 'Statements of Objects & Reasons' appended to the Bill, the Government explained that the Bill sought to centralise drug licensing in India on the basis of the recommendations by Dr. Mashelkar. In pertinent part, the 'Statement of Objects & Reasons' stated the following:

"The Committee, inter alia, recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of centralised licensing. The Central Government considered the recommendations of the

⁹ Statements of Objects & Reasons of Drugs & Cosmetics (Amendment) Bill 2005

Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations."

40. This Bill was referred to the Parliamentary Standing Committee on Health and Family Welfare for examination. In its 30th Report, this Standing Committee noted that during its interactions with 'drug manufacturers' associations, State Drug Controllers' associations, experts and also State Governments, a majority of them opposed the centralisation of drug licensing. The Standing Committee however expressed its agreement with the Mashelkar Committee report on this issue of centralising drug licensing activities (Para 9.22, 9.23). The relevant paragraphs of the Committee's reports are excerpted below:

9.22 In this regard, the Committee takes note of the specific recommendation for licensing of drug manufacturing units by the

Central Drug Administration made by the Mashelkar Committee after a detailed analysis of ground realities, recommendations of earlier expert Committees and views of all the stakeholders. Issue of non-uniformity of enforcement at the State level with regard to quality control of drugs was the main factor behind such a recommendation made by all the bodies like NRHC, Hathi Committee, Estimates Committee (Seventh Lok Sabha) and Mashelkar Committee. Committee's attention has been drawn by the guiding principle driving this suggestion, aptly summarized in para 33 of the Hathi Committee Report quoted below:-

"quality control of products manufactured anywhere in India was not solely the responsibility of the state in which the manufacturing unit is located, since the product is sold all over the country. If a unit in one state was allowed to manufacture and market a product of substandard quality, this would nullify the

measures taken by other States. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country."

9.23 The Committee agrees with the assessment made by all the earlier Committees that there was an urgent need for having a word class drug regulatory system in the country which can effectively handle the health concerns of one sixth of humanity. The Committee can only reiterate that wherever the health and safety of life of the people is concerned, cutting across regional/State specific interests/issues, the emphasis should be protecting the same.

41. Notwithstanding the support received from the Standing Committee, this Bill was withdrawn from Parliament by the government in 2013 when it introduced the Drugs & Cosmetics (Amendment) Bill, 2013 with the aim of implementing the aims of the Expert Committee

headed by Mashelkar in 2003. The Bill provided for the creation of a Central Drugs Authority (CDA) and unlike the previous bill, it specifically mentioned that the CDSCO would be the new CDA. The Bill also designated the DCGI as the central licensing authority – the DCGI would be responsible for the day to day functioning of the CDA, although the CDA itself would consist of several other members. In the "statement" accompanying the Bill, the Minister informed Parliament that the

...new Bill contains, inter alia, a revised approach to the centralised licensing, in respect of seventeen categories of very critical drugs included in the proposed Third Schedule to the Act....

In other words, instead of ensuring that licensing of all drug manufacturing in the country was centralized with a central authority, as recommended by the Expert Committee, the Bill in 2013 confined centralized licensing for manufacturing, sale & export to merely seventeen categories.

42. These seventeen categories were as follows: sera, solution of serum proteins intended for injection; vaccines, including DNA vaccines and vaccines containing living genetically engineered organisms; toxins; antigens & anti-toxins; Anti-biotics (betalactams and cephalosporins); Parenteral preparations meant for parenteral administration; Hormones and preparations containing hormones; r-DNA derived drugs; RNA interference based products; Monoclonal antibodies; Cellular products and stem cells; Gene therapeutic products; Xenografts; Cytotoxic substances (anti-Cancer drugs); Blood products; Modified Living Organisms. The Bill however gave the power to the Central Government to amend the Third Schedule to expand the number of drugs that are to be subject to the purview of centralized licensing. Regarding exports, the Bill considerably tightened regulation by centralizing all export licencing with the CDA.¹⁰ Thus exports of all drugs, regardless of whether they are mentioned in the Third Schedule, would be regulated by

the CDA. The Drugs & Cosmetics Act in its current form does not mention the word 'export' although the DCGI has claimed in an interview that it does issue license for exports.¹¹ It is not clear under what authority does the DCGI issue such licences because the Drugs & Cosmetics Act does not give it any powers to regulate exports as a separate area.

43. Like the previous Bills, this Bill too was referred to the Department Related Parliamentary Standing Committee on Health. As was the case earlier, several provisions of the Bill were opposed by the pharmaceutical industry and surprisingly, even the Ministry of Commerce. These objections related to the additional layer of regulation for exports and the centralized model of licensing to be followed for the seventeen categories of drugs in the proposed third schedule. The Committee accepted almost all points of opposition. It recommended dropping 'export' from the entire amendment since all manufacturing facilities were in any case required to follow good manufacturing practices.

¹⁰ Clause 24 inserting Section 18D

¹¹ Killigudi Jayaraman, *India's top drug regulator*, Nature Medicine Vol. 20(8) August (2014).

Some stakeholders also demanded the deletion of the proposed central licensing of 17 categories of drugs but the Ministry of Health made it very clear that deleting such a provision would go against the core of the Mashelkar Committee and the earlier reports of the Standing Committee.¹² In response to the strong plea made by the President of SME Pharma Industries Confederation, the Standing Committee recommended that the Ministry relook the decision to place Betalactams and Cephalosporins Antibiotics and Parenteral Preparations in the Third Schedule for central licensing. The SME Pharma Industries Confederation expressed concerns that “the centralization of drug licensing would kill the SME pharma units and further strengthen the already powerful MNCs”¹³ because centralization would allegedly increase compliance costs. In addition the Standing Committee also recommended doing away with the proposed CDA because it was large and unwieldy.

44. While the Drugs & Cosmetics (Amendment) Bill, 2013 was still pending in Parliament, the Ministry of Health, under the Modi Government, has invited comments on a new Drugs & Cosmetics (Amendment) Bill, 2015. This new version of the Bill has incorporated several changes recommended by the Standing Committee – including doing away with an added layer of regulation for exports and amending the Third Schedule to remove Betalactams and Cephalosporins Antibiotics and Parenteral Preparations from the Third Schedule – FDCs have however been included in the Third Schedule. It remains to be seen if the Government introduces this Bill in Parliament. Even if introduced in Parliament, it should be noted that this Bill does not comply with the recommendation of the Expert Committee in 2003, to centralize all drug licensing. In its current form the Bill centralizes licensing of only seventeen categories.

¹² 79th Report on the Drugs & Cosmetics (Amendment) Bill, 2013, Department Related Parliamentary Standing

Committee on Health & Family Welfare (December, 2013) at 68

¹³ *Ibid* at 23.

Section G: Is a legislative amendment required to centralize drug licensing activities in India?

45. An important question to answer at this stage is whether the government really needed to wait for legislative intervention by Parliament before it could centralize drug licensing activities in the country. As explained earlier, the distribution of licensing functions between the State and the Centre has taken place through the Drugs & Cosmetics Rules, 1945 – the Drugs & Cosmetics Act has delegated the function of framing the rules to the Central Government and via Rule 69, the Central Government has illegally sub-delegated its powers to State Government. Therefore, if the States have derived their licensing powers from Rules drafted by the Central Government, the latter can very well amend the Rules to take away these licensing powers from the respective State Governments. Thus, if the Central Government really was serious about implementing the recommendations of the Expert Committee to centralize licensing, it would have done so 12 years ago by amending the rules. The fact that it has not done so is indicative

of the reality that the Central Government is probably not very serious about following up on the recommendations to centralize drug licensing in India.

Part II – The weak investigation & enforcement mechanism under the Drugs & Cosmetics Act, 1940

48. The Indian model of enforcing standards of quality for drugs available to patients is very different from the model of regulation followed in developed western countries. While regulators in the west insist on checking quality at every stage of the manufacturing process, and documented evidence that Good Manufacturing Practices (GMPs) are followed at every step in the process, the entire regulatory process in India is focussed on checking the quality of the final drug product after it enters the markets.

49. The enforcement process in India begins with central and state drug inspectors drawing samples of commercially available drugs from pharmacies and hospitals in their respective jurisdictions and

dispatching these samples to government analysts in central and state laboratories for testing. Once the samples are tested, the report is sent to the drug inspector. If the drug is Not-of-Standard-Quality (NSQ) the inspector will typically conduct an investigation and take a call whether to prosecute the offending manufacturer based on certain guidelines. The manufacturer is normally served a notice to hand over documents related to manufacturing and provide an explanation. The manufacturer may also choose to appeal the decision of the government analyst by approaching the Central Drug Laboratory at Kolkata. Depending on the investigation, prosecution is initiated by the Drug Inspector filing a criminal complaint before the local criminal court, which after taking cognizance of the offence will issue summons to the manufacturer. After a trial, the court passes judgment on the innocence or guilt of the manufacturer based on the complaint filed by the drug inspector. A guilty manufacturer can be sentenced to a prison term along with a fine as mandated under the law. In order to determine the

efficacy of this enforcement mechanism, the authors of this report filed several RTI applications with several state and central authorities. From the replies received, it is obvious that there are severe flaws at each stage of the enforcement mechanism. This chapter will explain problems at each stage of the regulatory framework.

50. The larger issue which is at stake in this debate is whether the Indian model of ensuring quality of its drug supply is the most effective model of regulation for the country because the very act of random sampling of commercial drug supplies by drug inspectors when they purchase drugs from pharmacies and hospitals implies that not all drugs are scrutinised with the same rigour. Furthermore, resources allocated to inspectors vary widely among states which result in an uneven sampling of the drug supply. A fundamental reform of the regulatory process will require the Indian regulatory framework to stress compliance with GMPs at each and every stage of the manufacturing process since GMPs are designed to

ensure fool proof quality checks and accountability.

Section A - Sampling of drugs by Drug Inspectors and the flaws therein

51. The starting point for enforcement of quality standards under the Drugs & Cosmetics Act, 1940 is the drawing of samples of a drug from the marketplace by drug inspectors. These samples are then sent to government laboratories for testing by a government analyst, against the standards prescribed in either the Indian Pharmacopoeia or any of the other Pharmacopoeias such as the USP or BP. If a sample passes the quality check the matter ends there but if the sample fails a quality check, the government analyst returns with a finding that the drug is not of standard quality (NSQ). The drug inspector then may take a decision to further investigate and prosecute the case. Such a system of enforcement is antiquated and far from ideal because it is inherently inaccurate as it is based on a small sample of the total number of drugs actually sold in the market. In such a scenario, the process of drawing samples from the market place

becomes all the more important in a market like India. It is also necessary that these guidelines are based on a sound statistical model which covers a wide cross-section of the market. A failure to have well thought out sampling guidelines will skew the entire system of drug enforcement because the sampling guidelines are the starting point of the enforcement framework under the D&C.

52. In order to determine whether the drug inspectors at the level of the state regulator and central regulator were following a well-designed statistical model to draw samples from the market, we filed a series of RTI Applications with the CDSCO and a number of state level drug regulators, asking them the two following questions:

1. As per Section 23 of the Drugs & Cosmetics Act, 1940 a Drug Inspector is required to tender a fair price for any sample of Drug or Cosmetic picked up for the purpose of testing. In this regard the PIO is requested to provide the applicant with details of the amount sanctioned per inspector over the last 5 years, per year, for the purpose of

purchasing samples under Section 23 of the Drugs & Cosmetics Act, 1940.

2. While purchasing samples under Section 23, is a Drug Inspector required to follow any guidelines regarding the different types of drugs that are required to be drawn from the market for testing. Please provide the applicant with a copy of any such guidelines.

53. The first question was important because Drug Inspectors are required under law to tender a fair price for any drug sample that is purchased from a pharmacist. If an adequate budget isn't sanctioned for this activity, it would directly affect the type of drugs that can be purchased from the market. Drugs that treat diseases like cancer, injectable or extended release formulations are typically more expensive than Over the Counter drugs (OTCs). The second question was aimed at understanding the guidelines followed by each drug inspector for the purpose of drawing samples from the market in order to judge whether the sampling guidelines were based on a scientific statistical model. As discussed

above, lack of a sound statistical sampling model skews the entire process of sampling toward a few classes of drugs thereby rendering the entire operation ineffective. The replies that we received on both counts, demonstrated the degree of dysfunction within regulators on this relatively simple issue.

54. The CDSCO HQ declined to answer the RTIs, preferring instead to divert the applications to its zonal offices. This is a tactic frequently adopted by the CDSCO HQ while dealing with RTI applications. Three of the zonal offices provided answers: the East Zone (EZ), the West Zone (WZ) and the South Zone (SZ). All three zones claimed that there was no specific budget sanctioned for the purpose of drawing samples from the market and that money was generally drawn from the 'office expenses' head of the budget. None of these zonal offices gave us a specific reply on the amount of money that they spent on drawing samples – such accounts should be readily available with the accounts officers within these zonal offices. Given the critical role of sampling, it is quite surprising that the

CDSCO hasn't budgeted specifically for this task.

55. With regard to the second question, EZ and WZ did not even bother to provide a reply. The SZ provided a reply to the second question pointing to the ["Guidance Document for Functions and Responsibilities of Zonal, Sub-Zonal and Port Offices of CDSCO"](#). Page 15 of this document states that each drug inspector should collect at least 5 samples every month for testing from Government dispensaries, hospitals, CGHS dispensaries, rural outlets and from manufacturing premises. The document also makes mention of deputation of drug samplers to specifically carry out this function and that each sampler is required to purchase at least 20 samples per month from the fast moving and generic products. None of these zones referred to a circular from the DCGI's office dated 20.07.2010 which laid down different criteria: "5 samples from Government dispensaries, hospitals, rural outlets and from manufacturing premises during inspection." And "At least 5 survey

samples of drugs per month shall be collected from manufacturing premises as part of the inspection procedure. This may also include raw material samples from the stores of the manufacturers." Even this circular (which we found buried in a parliamentary report) does not require a scientific statistical model which would ensure testing of a cross-section of the drugs available in the market.

56. Of the State Governments who replied to us, we received a range of diverse answers. The regulator in Uttarakhand transferred our RTI applications to various drug inspectors within that state, none of whom actually provided us with details of either the amount they spent on sampling or the guidelines to help guide the drug inspectors on the sampling process. Their replies were mostly evasive and lacking any meaningful information. Similarly the regulator from Gujarat simply stated that no particular amount was sanctioned for this activity but failed to disclose the actual amount spent. It also stated that no guidelines were followed on how to draw samples. The Drug Controller

from Karnataka provided some guidelines in Kannada, which we haven't yet translated. Regarding the amount spent on drawing samples, the authority merely provided a copy of their entire budget outlay for the last 5 years without telling us exactly how much they had spent specifically on purchasing drugs for testing. Our application with the Maharashtra FDA was transferred from their HQ to the Office of the Joint Commissioner whose office promptly replied claiming that they had none of the information and that their HQ would provide the information. The only states which did provide us with some useful information were Kerala and Tamil Nadu.

57. The reply from Kerala provides a district-wise breakup of the amount spent on drawing samples. The highest amount drawn by an Assistant Drug Controller (ADC) in any district was Rs. 1,13,800 by the ADC (Kollam) in 2013-014 and the lowest amount for an ADC was Rs. 12,500 by the ADC (Ernakulam) in 2013-14. A separate breakup is provided for Drug Inspectors (DI), with the highest amount being Rs. 48,657 in

2012-13 by the DI of KTM zone, while the lowest was Rs. 1,700 by the DI of WD zone in 2014-15. The high variance in the budget allocated in different zones could be due to many reasons such as population size etc.

58. On the issue of guidelines, Kerala informed us that there were no guidelines that it followed while drawing samples.

59. The reply from Tamil Nadu was by far the most detailed and extensive. The HQ of the Tamil Nadu Food Safety & Drug Administration (TNFSDA) transferred our RTI application across to the public information officers in all zones across the states. Tamil Nadu is perhaps the only state in the Union where money is specifically budgeted for the purpose of drawing samples. Most of the individual zones provided a list of the amount that they had spent on this activity. For example Zone III in Chennai city spent an average of Rs. 40,000 every year on drawing samples while Zone II spent Rs. 93,000 in 2014-15 and Rs. 60,000 last year. The Virudhnagar Zone started off with spending only Rs. 12,000 in 2011-12

before its spending increased to Rs. 50,000 in 2014-15, 2015-16. Other zones like Vellore spent close to Rs. 40,000 last year while the Thanjavur zone spent Rs. 1,74,754 last year on drawing samples from the market. One of the lower spending zones was the Thiruvallur zone which spent only Rs. 16,000 in 2014-15 before hiking spending to Rs. 30,000 for 2015-16.

inspector to draw 7 samples from the market with at least 3 samples being drawn from government hospitals. The guidelines also states that sampling should be planned well in advance; judicious and drawn from all categories of drug administered on the human body. Since many drug inspectors replied that there were no guidelines, they clearly don't even know about the existence of these guidelines. In any event, these guidelines are far from adequate. Drug inspectors need to be given much better instructions to ensure that a wide cross-section of drugs are covered in each market.

60. Tamil Nadu as a whole appears to be spending a significant amount of money on drawing samples for testing. Although, it is still an open question whether the amounts sanctioned are adequate to purchase more expensive medication for diseases like cancer, which can cost thousands of rupees per vial or capsule.

62. Since the sampling process is itself so bereft of method or science, it follows that the rest of the enforcement mechanism is built on a faulty foundation. Even more alarming is the lack of adequate information within these individual regulators about their own guidelines. First, there needs to be a national set of guidelines on how sampling from the market is to be conducted. Such guidelines need to be developed by a reputable institution like the Indian Statistical Institute. Further, budget needs to be

61. On the issue of guidelines, we received widely inconsistent answers from the different zones within Tamil Nadu. While some zones claimed that there were no guidelines, other zones like Coimbatore did provide us with a copy of guidelines issued on 8.1.2003 by the Director of Drugs Control, Tamil Nadu. These guidelines basically require each drug

specifically allocated to each state, across each district and tracked in a transparent manner so that the people of the country know how their tax monies are being spent. Finally, the current guidelines do not include samples from private pharmacies, which are the largest suppliers of drugs to the general public. This is a serious gap.

63. Ideally, India needs to move away from this archaic process of relying on sampling commercial supplies to establish quality of their drugs. This process does not address issues like stability of the product. While a commercial supply recently manufactured may pass a dissolution test, a product which is closer to its expiration date may not. The current process doesn't make any accommodation for this and similar issues. Testing for quality in commercial supplies is not an effective way of establishing quality of our drug supply. However, as long as this process of sampling continues in India to establish quality of drug supply, the process can be better regulated by the framing of

rules under the Drugs & Cosmetics Act, 1940.

Section B: The offences in the Drugs & Cosmetics Act and the circumvention of these offences through the DCC guidelines;

64. There are four main offences under the Drugs & Cosmetics Act pertaining to the quality of drugs: Not of Standard Quality (NSQ) drugs, Spurious Drugs (basically counterfeit drugs), Adulterated Drugs and Misbranded drugs. Contrary to general public opinion, the biggest problem faced in India is not spurious drugs but rather NSQ drugs. This fact is substantiated by the government's own reports. 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. Despite posing a serious problem to public health, manufacturers of sub-standard drugs are not prosecuted as vigorously as required under the law. This is due to

guidelines set out by the prosecution which is in effect circumvent the statutory legislation.

65. As per Section 16 of the Drugs & Cosmetics Act, 1940, standards of quality required to be followed in India for medicines are laid down in Schedule II to the Act. This schedule recognizes the standards described in the Pharmacopeia of various countries including the Indian Pharmacopeia. When samples are drawn from the market, they are tested as per the standards prescribed in the Pharmacopeia adopted by the manufacturer. These standards can be viewed on the labelling of the drug. For example, most Indian drugs will bear the phrase "IP" to demonstrate that they are following the standards laid down in the Indian Pharmacopeia. The Indian Pharmacopeia provides a reference standard, which is established and maintained by the Indian Pharmacopeia Commission (IPC) – which functions directly under the Ministry of Health & Family Welfare (MOHFW). When samples of drugs are drawn from the market by drug inspectors and sent to government

laboratories for analysis, they are tested as per the protocols established in the IP. Each sample is usually tested for content of active ingredient, its dissolution profile, disintegration, visual description and uniformity of weights. Each one of these tests is important to establish whether a drug will have therapeutic value for the indication it is prescribed and explained in greater detail below.

66. An assay test, aimed at establishing the content of the active ingredient, is important because it tests the quantity of the active ingredient in the tablet against the quantity advertised on the labelling. The IP usually allows for a 10% margin of error; i.e., the assay result can be between 90% and 110% of the quantity advertised on the labelling. If the API is above or below these limits, the drug will likely not have its intended effect and may in some cases – depending on the disease – cause grievous hurt or death to the patient. Similarly if a drug fails a dissolution test or disintegration test, the drug is very likely to not dissolve into the blood stream of the patient according to the prescription parameters and can either have little or absolutely no effect on the

medical condition that it is supposed to treat. Again, depending on the medical condition, the failure of such a drug may cause grievous hurt or death to the patient. In either case, once it is established that the drug has failed the standards laid down in the IP, the govt. analyst will declare the drug to be NSQ and as per the Drugs & Cosmetics Act, 1940.

67. As per the prevailing law, manufacturers of such NSQ drugs have to be prosecuted under Section 18(a)(i) read with either Section 27(a) or Section 27(d) of the Drugs & Cosmetics Act. However the reality of enforcement in India is very different because of the Drugs Consultative Committee (a statutory body consisting of representatives of all state drug controllers, the DCGI and the central government) has passed certain guidelines in 2008 with the specific intent of diluting the spirit of the amendments brought by Parliament in that very same year. These were called 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" and were decided at the 40th meeting of the DCC.

68. These Guidelines prescribed by the DCC diverge significantly from the scheme of prosecution laid down under the Drugs & Cosmetics Act. The DCC guidelines create three different categories: Category A, Category B & Category C according to the nature of defect and recommend a different form of legal action for each series. For instance, Category A basically deals with spurious or counterfeit drugs where stringent criminal prosecution is recommended. Category B deals with cases of grossly sub-standard drugs – such drugs are basically those drugs which have less than 70% of the API that was advertised on labelling, drugs which fail disintegration tests, dissolution tests, parental preparations failing sterility tests, vaccines failing in potency tests, presence of any adulterant which renders the product injurious to health. For Category B defects, the Guidelines prescribe criminal prosecution only if the drug inspector feels that the defects are

due to gross negligence or criminal intent and only if milder punishments like suspension or cancellation of manufacturing licences are an inadequate punishment. Category C defects, which are listed as minor defects, are described as “defects arising out of minor variations in quality” because of “inadequate pre-formulation development studies, lack of in process controls exercised by the manufacturer or unsuitable conditions under which drugs are stored or transported”. This class of defects includes, “broken or chipped tablets”, “presence of spot/discolouration/uneven coating”, “cracking of emulsions”, “clear liquid preparations showing sedimentation”, “change in colour of the formulation”, “isolated cases of presences of foreign matter”, “labelling errors”. In case of these Category C defects, the guidelines recommend administrative actions like suspension of licence as the first reaction with criminal prosecutions recommended only for those cases where administrative procedures are considered inadequate.

69. These guidelines are illegal and liable to be struck down as unconstitutional for two reasons.

70. The first illegality is that the Guidelines essentially bypass the binding standards that are recognised by the Drugs & Cosmetics Act and dilute the requirement to initiate criminal prosecution in all cases where quality is breached. As explained above, the standard recognised per Section 16 of the Act are those of different Pharmacopoeias mentioned in the Second Schedule to the Act. These pharmacopoeias lay down their own acceptable margin of error in “assay tests” which are basically used to test the content of active ingredient in a drug. The Indian Pharmacopoeia (IP) for example lays down a margin of error of 10% i.e. if the active ingredient is between 90% and 110%, the drug is deemed to be within quality parameters. The moment the content of the active ingredient goes beyond these parameters, a drug is classified as NSQ by a government analyst. As per the Drugs & Cosmetics Act, the manufacturer of the NSQ drug should be prosecuted according to the law.

However, the DCC guidelines lay down a margin of error of 30%. It is only when the active ingredient falls below 70% that the defect is listed as a Category B defect and criminal prosecution is recommended. In all other cases the DCC guidelines recommend only suspension of licence under the Drugs & Cosmetics Act – the issue of why suspension of licences are ineffective are discussed in a different chapter. Similarly, the DCC guidelines, recommend suspension of licence rather than criminal prosecution in cases where a drug fails dissolution or disintegration tests – Category B defects. The IPC however classifies products which fail either dissolution or disintegration test as NSQ thereby mandating criminal prosecution under the Drugs & Cosmetics Act. Since the IP is formulated by an expert body called the Indian Pharmacopoeia Commission (IPC), it is pertinent to question the intent of the DCC to dilute the standards laid down by the IPC. The specific legal question that arises in this context is whether the DCC, which lacks the authority to make law, can legally dilute binding standards

recognised by Parliament through Section 16 of the Drugs & Cosmetics Act by prescribing its own standards? The answer is quite simple. The DCC, though a statutory body, has no law making powers and it cannot dilute the standards prescribed by a superior body like Parliament. Moreover, the courts have clearly held that standards set by expert bodies will always prevail. As per the judgment of the Kerala High Court in the case of *State of Kerala v. Vasudevan Nair* (1974 KLT 617 (FB)) quality standards are binding and have to be observed strictly. In pertinent part, the Court held “The standards of qualities are fixed by the Government after due deliberation and after consulting a committee of competent men, it is for them to give due allowance of probable errors before fixing a standard. When a standard has been fixed it has to be observed strictly.” Thus, clearly these guidelines appear to be illegal.

71. The second illegality with the DCC Guidelines is that it requires Drug Inspectors to ascertain the criminal intent or negligence of the part of the manufacturer while making a decision whether to prosecute a NSQ case. In

pertinent part, the guidelines state *“In the case of drugs manufactured by a licensed manufacturer under a valid manufacturing licence and found grossly sub-standard and where criminal intent or gross negligence is not established, weapon of prosecution should be used judiciously, where it is felt that administrative measures like suspension or cancellation of licenses or compounding of offences would not meet the ends of justice.”* This aspect of the guidelines is completely contrary to the elements of Section 27 of the Drugs & Cosmetics Act, 1940 since that provision imposes a strict liability standard on all defendants i.e., irrespective of mental intent, if a defect has been found, the manufacturer is required to be prosecuted and punished. In case the defect is of a nature that can lead to death or grievous hurt of a patient, the manufacturer can be jailed for life. In other cases, the prison term usually extends to only three years with a mandatory minimum of one year. It is fair then to ask why is it that the DCC felt compelled to reduce a legally binding standard for prosecution for

manufacturers of NSQ drugs; which are the real problem with the drug supply in India?

72. The Indian drug industry has for long demanded the dilution of this standard. For example in a submission to the Committee on Petitions of the Rajya Sabha in 2013, the Indian Drug Manufacturer's Association (IDMA) asked for the law to be amended to make *mens rea* a required element of such offences. The relevant portion of the IDMA's submission is extracted below:

The Drugs and Cosmetics Act, 1940 casts absolute liability on every person engaged in manufacture, sale and distribution of drugs and cosmetics. The absence of mens rea is not considered as defense in trial of offences under the Drugs and Cosmetics Act, 1940. As a result, a bona fide mistake committed during the course of routine manufacturing operations and the clandestine / and intentional manufacture of spurious and adulterated drug is placed on the same footing and no distinction

is made between the bona fide licensed manufacturer and the unscrupulous elements involved in clandestine activity of manufacture, sale and distribution of spurious and adulterated drugs. It is therefore necessary to amend Section 27 of Act to include mens rea as in most of the cases where penalties like life imprisonment are there.

73. The 148th report of the Committee on Petitions accepted this recommendation stating: "The Committee therefore strongly recommends amending Section 27 of Act to include mens rea". The government has so far not moved any amendment in Parliament and *rightly so because it is an illogical recommendation*. Sub-standard drugs are made due to negligence of the manufacturer and negligence never has a *mens rea* or mental intent. By eliminating *mens rea*, the law places a higher onus on the industry to deliver quality products to the market. It is pertinent to mention that similar provisions existed even under the Prevention of Food Adulteration Act,

1954. Those provisions had been challenged as unconstitutional. However the Supreme Court upheld the provisions in the case of *Andhra Pradesh Grain and Seed Merchants Association etc. v. Union of India* (AIR 1971 SC 2346). In pertinent part, the Court justified the elimination of *mens rea* on the following grounds:

"7. It is true that for the protection of the liberty of the citizen, in the definition of offences, blameworthy mental condition is ordinarily an ingredient either by express enactment or clear implication: but in Acts enacted to deal with a grave social evil, or for ensuring public welfare, especially in offences against public health, e.g., statutes regulating storage or sale of articles of food and drink, sale of drugs, sale of controlled or scarce commodities, it is often found necessary in the larger public interest to provide for imposition of liability without proof of a guilty mind.

8. If from the scheme of the Act it appears that compliance with the regulatory provisions will be promoted by imposing an

absolute liability, and that it cannot otherwise be reasonably ensured, the Court will be justified in holding that the restriction on the right of the trader is in the interest of the general public. Adulteration and misbranding of foodstuffs is a rampant evil and a statute calculated to control that evil is indisputably in the interest of the general public: The statute imposing restrictions upon traders will not be deemed unreasonable merely because it makes a departure from the normal structure of statutes enunciating offences and prescribing punishments.”

74. Returning to the issue of Guidelines, since the Drugs & Cosmetics Act classifies offences as per the nature of the defect and not the intention of the manufacturer, the DCC cannot circumvent the guidelines by requiring the drug inspector to identify the *mens rea* of the manufacturer before deciding to initiate a criminal prosecution against the offending manufacturer. As per the law, once a government analyst detects a drug to

be NSQ, a criminal prosecution is necessarily mandated under the law. The DCC has no authority in law to prescribe guidelines that subvert the legislative intent guiding the Drugs & Cosmetics Act.

75. There is a very strong case for a court of law to declare the guidelines to be *ultra vires* the Drugs & Cosmetics Act. More importantly, the membership of the DCC needs to be closely examined. This statutory body has become a de-facto spokesperson for the industry. Providing a shield for manufacturers who make questionable product has become the primary objective of this body.

Section C: The often flawed investigation & prosecution process followed by Drug Inspectors

76. The most critical component of drug enforcement is the quality of investigations and prosecutions by drug inspectors across the country. This in turn depends on the quality of drug inspectors themselves. While some drug inspectors are undoubtedly competent, High Courts across the

country have expressed grave concern regarding the quality of most drug inspectors. 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.

77. 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."

78. In order to understand the variety of problems with the investigation and the prosecution process as it is implemented on the ground, the authors of this report filed applications under the Right to Information Act for copies of criminal complaints filed by drug inspectors before criminal courts in three different states: Andhra Pradesh, Tamil Nadu and Maharashtra. Since criminal complaints contain all details of the investigation, it is possible to analyse possible problems with the investigation process. Summaries of a few of these complaints are available below, followed by an analysis of the various problems commonly encountered in investigations and prosecution of manufacturers of NSQ drugs.

79. **Drug Inspector, State of AP v. Quest Laboratories Pvt. Ltd. & its Managing Director before the Court of the Judicial First Class Magistrate at Vizianagaram:**

In this case, the Drug Inspector visited the Central Drug Stores at APMSIDC (AP Medical Services and Infrastructure Development Corporation) located in the cantonment area of Vizianagaram and drew samples of Tinidazole tablets IP 300 mg, Batch No. 02, Mfg. date: 11/09, Exp date: 10/11 manufactured by Quest Laboratories Pvt. Ltd. which is located at Indore in Madhya Pradesh. Tinidazole is an anti-parasitic drug used to treat a variety of amoebic and parasitic infections.

80. These samples were drawn by the drug inspector on January 2, 2010 and sent to the Drugs Control Laboratory, Hyderabad for testing. The test report declaring the sample to be NSQ was sent back to the drug inspector only on July 21, 2011; it took 19 months for the lab to complete its analysis. It is safe to assume that the entire batch of this product had already been consumed by patients by the time it was declared NSQ! The government laboratory found that the drug had failed disintegration test. Disintegration test is conducted to

establish the time it takes for a tablet to completely disintegrate in a chosen medium. If a tablet fails a disintegration test, it means that the tablet has been manufactured incorrectly, for example it could be compressed with inadequate strength. The failure of a tablet to disintegrate properly will affect the way it dissolves in the stomach and its bioavailability. This has a direct impact on the therapeutic efficacy. In the worst case, failure of a disintegration test makes consumption of the drug the equivalent of eating chalk. In serious cases of infection, the failure of a drug like tinidazole can possibly result in the death of a patient.

81. The drug inspector served a copy of the report from the government lab under Section 24(2) on the pharmacist the same day that he received it along with a notice under Section 18A requiring the pharmacist to disclose the name of the manufacturer and the source of the drugs. This notice is important in order to establish the custody of the supply chain from the manufacturer to the pharmacist. A week later, on July 28, 2011 the pharmacist responded to the drug inspector that a batch of 100,000

tablets had been procured from the manufacturer on 10/12/2009.

82. On the basis of this information, the drug inspector wrote to Quest Laboratories (A1- Accused No.1) on July 20, 2011 with a copy of the test report and a sealed portion of the sample that was drawn from the pharmacy informing the company that it was required to furnish the following details: drug license, list of approved products, constitution particulars, batch manufacturing records and distribution particulars. **The company never replied to the notice.** A reminder notice was sent on September 8, 2011 and another notice was sent on October 25, 2011 and yet another notice on May 11, 2012. The company apparently didn't think it was necessary to respond to any of the notices.

83. After failing to receive responses to all 4 notices, the drug inspector proceeded to file a criminal complaint on June 7, 2012 before the Court of the Judicial Magistrate First Class at Vizianagaram accusing Quest Laboratories and its Managing Director of manufacturing and selling NSQ drug under Section 27(d), failure to furnish information and

maintain records as required under Sections 18B, 24, 22(1) (cca), 22(3), 28A of the Drugs & Cosmetics Act, 1940.

84. The time between drawing the sample of the drug (January 2, 2010) and filing of the criminal complaint (June 7, 2012) was therefore 30 months. The time elapsed between the receipt of the test report (July 21, 2011) and filing of the criminal complaint (June 7, 2012) was almost a year. Since this case was listed as pending in the list provided us in the middle of last year, it means that the prosecution has dragged on for more than 3 years – a long time, for a simple case.

85. Apart from delays, also appalling is the manner in which the investigation were conducted. For example, if an accused isn't responding to notices for information pertaining to the investigation, the drug inspector investigating the case should ideally enter the premises of the accused and seize the records and documents required for the criminal investigation. This happen with Ranbaxy when the US Marshalls conducted a raid on its offices in Princeton, NJ in February 2007. In the present case, the drug inspector

most likely did not have the jurisdiction to exercise such powers because Section 22 of the D&C Act is quite clear that a drug inspector can exercise search and seizure powers only within the local area for which he has been appointed (AP). In such a case, there is nothing preventing the drug inspector from writing to his counterparts in either the CDSCO or in the state drug regulator in Madhya Pradesh (MP) where the drug was manufactured to seek their co-operation. At the very least, one would expect that the licensing authority in MP be informed of the sub-standard medicine detected in AP. The complaint is silent on whether any such attempt was made. By filing a criminal complaint without seeking the batch manufacturing records or testing the stored reference samples, the entire prosecution is weakened.

86. [Drug Inspector, State of A.P. v. Sri Lakshmi Agencies & its Proprietor before the Court of 2nd Addl. Judicial Magistrate, First Class, Bhimavaram District](#): We specifically selected this case because the prosecution list showed the manufacturer to be a Chinese company by the name M/s

Quzhou Werong Pharmaceuticals and Chemicals Co. Ltd.

87. The copy of the criminal complaint provided to us narrated the following facts: On May 5, 2011, the Drug Inspector of the Bhimavaram District conducted a raid on the Pharmacy Sri Lakshmi Agencies and discovered that the shop was stocking for sale certain drugs, etc. without the required licences under the Drugs & Cosmetic Act, 1940. Such raids are a fairly common practice in India. During the course of the raid, the Drug Inspector also picked up some "powders" as a sample for analysis and dispatched the samples to the Drugs Control Laboratory (DCL), Vijayawada on May 22, 2011. A few days after the raid, on May 13, 2011 the proprietor of the shop was served notice under the provisions of Section 18-A ad Section 22(1) (cca) of the D&C Act, 1940 directing him to disclose the source of purchase in order to establish the chain of custody of supply. In the meanwhile, the Drug Inspector procured certain details of the shop from the Commercial Tax Officer and discovered that the shop in question

had actually been registered for fish and prawn medicines and had a turnover of Rs. 41 lakhs over 5 years.

88. A couple of weeks later on June 9, 2011, the proprietor replied that he was unable to produce the purchase bills of the drugs. The containers seized by the Drug Inspector however mentioned that the importer of the drug was Medipharma Drug House in Mumbai. On September 23, 2011, the Drug Inspector issued notice to this importer requiring them to produce the photocopy of the import license and sales particulars. The letters was returned as undelivered.

89. On October 18, 2011, the DCL sent back the test reports stating that the samples seized, now disclosed to be Oxytetracycline, were not compliant with the standard laid down in the BP. Oxytetracycline is a broad-spectrum antibiotic, in addition to human use, it is also used on animals. The reports were served on the accused and on the same day a fresh letter was addressed to the importer Medipharma Drug House requiring it to produce the import license and sales details latest by December 1, 2011. The importer replied

this time claiming that they neither imported the products in question nor sold it to the accused and that the seized products did not belong to them. The drug inspector took the claim at face value and prosecuted only the firm found to be selling the drug in question.

Inspector on February 23, 2010 picked up samples of Glucored forte tablets, manufactured by Sun Pharmaceuticals in Jammu & Kashmir (J&K) and samples of Primolut N manufactured by Zydus Healthcare in Sikkim from the shop of accused no. 1 located in Machilipatnam district. Both samples failed quality control tests. The pharmacist had failed to maintain receipts as required under the law to demonstrate the supply chain of custody of these drugs. Unlike the other cases, the drug inspectors investigating this case, travelled to J&K and Sikkim respectively and contacted their counterparts in those states before meeting the manufacturers themselves. Both Sun Pharmaceuticals and Zydus denied that the drugs in questions had been manufactured by them. The reasons provided by Sun aren't very clear from the complaint. Zydus claimed that the packaging of the seized samples was different from the control samples for the batch in question. The drug inspector seems to accept this reasoning and files the complaint only against the pharmacist and some of the other persons from

90. Although the investigation in this case moved forward relatively quickly, the investigation was hardly satisfactory. Ideally, the drug inspector should have contacted the CDSCO to cross-check Medipharma's claims because imports are regulated only by the CDSCO. If this procedure had been followed, CDSCO would have been able to corroborate Medipharma's import licences and verify whether any drugs had been imported from Quzhou Werong Pharmaceuticals and Chemicals Co. Ltd. Unfortunately, none of these procedures seems to have been followed.

91. [**Drug Inspector, State of A.P. v. Sri Venkata Ramana Medical and Fancy Stores & Ors**](#) before the Court of the 2nd Addl. Judicial First Class Magistrate, Machilipatnam: In this case, the Drug

whom he has claimed to have sourced the drugs.

92. While this case saw much better inter-agency co-ordination, the failure of the drug inspector to explain in detail his reasons for accepting the explanation given by both Sun Pharma and Zydus that neither of the drugs were manufactured by them is disappointing. Faced with a charge that they were manufacturing sub-standard drugs, the safest defence for a pharmaceutical company is to claim that the samples in question are fakes of their products. Unfortunately, there is no national process available to verify the veracity of these claims. In an ideal outcome, the drug inspector should carefully examine such claims and provide a scientific reasoning for either accepting or discounting such claims in the criminal complaint rather than take the easy way out by prosecuting only the pharmacist.

93. [**Drug Inspector, State of Maharashtra v. Medisys Biotech Private Limited & Its Directors**](#) before the **Chief Judicial Magistrate, Nagpur**: This was a relatively simple case, which was investigated and prosecuted within a

short period of time. The starting point for this case was when the Drug Inspector of the Nagpur Zone, drew samples of 'Neuropat-NV' tablets (Vitamin B1) from a pharmacy in Nagpur. The drug in question was manufactured by Medisys Biotech Pvt. Ltd. which is a pharmaceutical company based out of Himachal Pradesh (HP) – a state which is the fountainhead of Not of Standard Quality (NSQ) drugs in India.

94. The sample was drawn on February 3, 2012 and sent shortly thereafter to the Drug Control Laboratory in Mumbai for testing. The lab sent back the test report declaring the drug NSQ on April 20, 2012. The report explained that the drug was NSQ because "Content of Vitamin B1 in the sample is less than the permissible limit (i.e. 18%) of the labelled amount." Thereafter, the drug inspectors traced the supply chain by serving notices on the pharmacy from where the drug was sampled. The pharmacy revealed the name of the trader who had sold the drug – this trader in turn named another trader, who in turn revealed that it had

procured 20,000 tablets from the manufacturer – Medisys Biotech.

95. The drug inspector thereafter travelled to HP on May 19, 2012 and personally served on Medisys Biotech, a copy of the analyst's report and sealed portions of the samples drawn from the pharmacist in Nagpur. The company was also required to furnish details on its drug licence, its manufacturing record, testing record, analytical record, purchase detail of raw material, sale details of the drug in question. The company was informed that they had a right to appeal the findings in lab report by having a portion sent to the Central Drug Laboratory in Kolkata for confirmation. The company however declined to exercise the option and co-operated with the drug inspector by furnishing some of the required details. The investigation revealed that the batch strength was a total of 100,000 tablets. On receiving permission from the Joint Commissioner, the Drug Inspector initiated prosecution by filing a criminal complaint before the Court of the Chief Judicial Magistrate on August 24, 2012

96. The investigation thus was wrapped up in a record time of less than 7 months and the criminal complaint is adequate to ensure a successful prosecution especially since the manufacturer declined to challenge the test report. The complaint could however include more details on why the drugs had such low quantities of the API. In specific, to ensure a water-tight complaint, the drug inspector should test even the reference samples which are required to be stored by the manufacturer as a part of the GMP requirements under Schedule M of the Drugs & Cosmetics Act, 1940. Testing these samples will eliminate any claims by the manufacturer blaming the quality of the drug on the storage conditions at the pharmacist.

97. [Drug Inspector, State of Maharashtra v. Perennial Medicare & Ors.](#) **Before the Court of Chief Judicial Magistrate, Nagpur:** The starting point in this case was the drawing of samples on February 29, 2012 by a Drug Inspector from a pharmacy in Nagpur. The samples in question were OPTIMOX-CV powder for oral suspension – the Optimox brand belongs to Troikaa

Pharmaceutical Ltd. Although the supply chain led the drug inspector to Troikka in this case, the company quickly proved that it wasn't the manufacturer and that it had procured the drug from Perennial Medicare, a partnership firm based in the state of Himachal Pradesh (HP), which accepted that the drug in question was its product. It is likely that the trademark was licensed to the manufacturer or that the drug was manufactured on behalf of the trademark owner.

98. The investigation had been triggered by the fact that the sample was found to be NSQ in a test report of the Drugs Control Laboratory, Mumbai on May 2, 2012. The government analyst had declared the sample NSQ because *“Content of Clavulanic Acid in the sample (when freshly prepared) is less {1.77% of the labelled amount} than IP 2010 limit as given in the protocol and the content of Clavulanic Acid in the sample (when stored) is less {0% of the label amount} than IP 2010 limit as given in the protocol”*. Optimox is reportedly a FDC consisting of Amoxicillin and Clavulanic Acid – both are antibiotics. If the Clavulanic Acid content is close to nil, as is the case in

the situation, it will result in the antibiotic combination not working as expected. Since such antibiotics are most commonly used to combat infections, the failure of the drug to work can lead to deadly consequences in a patient. In this case, the batch in question had a total of 8984 bottles of this drug, all of which were sold to Troikka Pharmaceuticals, of which a total 2,548 bottles were supplied to Troikka Pharmaceutical branch in Nagpur which then sold 350 bottles to the pharmacy from where the Drug Inspector had drawn the samples.

99. On receiving the NSQ report, the Drug Inspector dispatched a copy of the test report along with the sample to Perennial Medicare on May 11, 2012. The complaint then records how the accused company replied on June 13, 2012 claiming non-receipt of the test report, to delay the investigation. According to the drug inspector, these tactics were deliberately used because the drug in question was reaching its expiry date rapidly. Although the complaint does not clearly outline the consequences of the batch reaching its expiry date, we can presume that the prosecution would be jeopardised

because the accused would not be able to exercise his right to appeal against the test report to the Central Drug Laboratory (CDL). In any case, it appears that on receiving confirmation from Troika in July, 2012 that Perennial Medicare was indeed the source of the NSQ drugs, the Drug Inspector responded by seizing the stock from the pharmacy in Nagpur, almost 2 months after the test report had already declared the sample NSQ.

100. Although the prosecution in this case was initiated quite quickly, the fact remains that this complaint is weak on two counts. Not only did the Drug Inspector fail to record the response of Perennial Medicare; there has been no attempt to procure the batch manufacturing records and other details. If the manufacturer was refusing to volunteer this information the Drug Inspector should have teamed up with his counterparts in either HP or at the CDSCO north zone to conduct a surprise raid to seize all the documents in question. Instead the Drug Inspector has filed a weak criminal complaint.

101. [Drug Inspector, State of Maharashtra v. Colinz Laboratories Ltd., Shefa Healthcare Pvt. Ltd. & Ors.](#) before the **Court of Chief Judicial Magistrate, Jalna**: This complaint was perhaps one of the shortest complaints that we have seen during the course of our research. Basically, the Drug Inspector, drew a sample of the drug, named 'Pasam' on February 29, 2012 and dispatched it to the government lab for testing on March 1, 2012.

102. The lab replied with the test report on October 8, 2012 (*7 months after receiving the sample*) declaring the drug to be NSQ. The drug in question, 'Pasam' is a combination of Simethicone (an anti-foaming agent which is used in treating bloating or discomfort caused due to excessive gas) and Dicycloverine (an anticholinergic which is used to treat muscle spasms and cramping in the gastrointestinal tract – basically a muscle relaxant). The sample was declared NSQ with the remark that *"The content of the dicyclomine hydrochloride in the sample is less (23.30% of the said amount) than the permissible limit. (Permissible limit:- Not less than 90% of the said Amount)"*.

103. On receiving the report, the drug inspector served notice on the pharmacist who reported that the drug was purchased from Colinz Laboratories – the company which is located in Mumbai, also appears to own the 'Pasam' brand. When notice was served on Colinz, it responded to the drug inspector that the drug was actually manufactured under a loan licence by Shefa Healthcare Pvt. Ltd. and provided the details to that effect. The company also asked Shefa Healthcare to provide with the Drug Inspector the necessary documents regarding the manufacture of this product. The complaint does not state which documents which were requested and whether Shefa Healthcare actually provided any of these documents. Instead the complaint directly skips to the fact that the HQ granted sanction to prosecute on October 20, 2012. It then took the Drug Inspector, another 5 months to actually file the complaint on March 21, 2013. Thus, the complaint was filed more than year after the sample was drawn.

104. Unlike other drug inspectors, this particular inspector charged the pharmacist as well from whom the drugs were sampled.

105. Of all the complaints that were studied for this report, this is one of the more poorly drafted. Unlike other cases where the manufacturer was located in an entirely different state, the manufacturer in this case was located in the same state. Although the Drug Inspector for Jalna District would not likely have jurisdiction over a manufacturer located in Mumbai, it would have been considerably easy to co-ordinate with the drug inspector in that zone since both of them belong to the same agency. However this was not done.

106. [**Drug Inspector, State of Maharashtra v. Akums Drugs & Pharmaceuticals Ltd. & Ors. Before the Court of Chief Judicial Magistrate, Jalna:**](#) The drug sample in this case was drawn on July 17, 2012 by the Drug Inspector from a company with a licence for the wholesale business. The drug drawn from the market was "Acemiz-S", which is a FDC of Paracetamol, Serratiopeptidase & Aceclofenac Tablets. While

paracetamol is used to treat fever, Aceclofenac is a non-steroidal anti-inflammatory drug which is used to provide relief from pain and inflammation of the joints. [Serratiopeptidase](#) is supposed to have anti-inflammatory properties, although this remains controversial. This FDC is indicated for pain relief and swelling of joints. Although many websites indicate Lupin as the manufacturer of the brand, it appears that Lupin is only the owner of the brand because in this case Lupin indicated to the drug inspector that although it marketed the drug, the manufacturer was Akums Drugs & Pharmaceutical Ltd. whose plant is located in Uttarakhand.

107. The Drugs Control Laboratory, Aurangabad declared the sample to be NSQ with the comment that *"The Content of the Serratiopeptidase in the sample is less (24.93% of the said amount) than the permissible limit: - Not less than 90% of the said Amount.)"*.

108. Once the supply chain to Akums was established, the Drug Inspector served a copy of the test report and sample on the company and asked them to furnish the "documents". The complaint

doesn't mention which documents were requested. The complaint then notes that Akums did provide some documents but neither mention's nor discusses the content of those documents. The company refused to confirm whether the sample belonged to it because the drug inspector had supposedly not established the supply chain to the company. After receiving permission from HQ a prosecution was launched on March 19, 2013.

109. Once again this complaint is short on details with no mention of the details contained in the batch records or even whether the inspector has studied the batch records to establish compliance with manufacturing standards.

110. [**The Drugs Inspector, State of Tamil Nadu Alfred Berg & Co. Pvt. Ltd. and Ors.**](#) **before the Honourable Court of Judicial Magistrate Gudiyattam:** In this case, the drug inspector drew samples of Glipizide tablets manufactured by Alfred Berg & Co from the premises of the Government Hospital, Gudiyattam, Vellore and sent it for lab analysis on August 22, 2013. The lab report which was returned on December 10, 2013 reported that the sample didn't

conform to the IP specification for Glipizide and that the sample in question was actually Glibenclamide. The drug was therefore declared to be 'Not of Standard Quality' and 'Spurious'. Both Glipizide and Glibenclamide are anti-diabetic drugs from a class of medication known as 'sulfonylureas'. While the latter was discovered around 1966, the former was made available in the market only from 1984. There can be serious medical complications for elderly diabetic patients who have consumed Glipizide instead of Glibenclamide. In fact, [a WHO report](#) comparing the two drugs says "The data unequivocally recommends against the use of glibenclamide in elderly patients."

111. On receiving the govt. analyst's report, the drug inspector inspected the stocks of the Government Hospital on December 18, 2013 and discovered that there was nothing left of the stock. A notice was served on the chief pharmacist of the government hospital to disclose the details of the person from whom the drugs were procured. The chief pharmacist responded on the same day disclosing that the

drugs had been procured from the Tamil Nadu Medical Services Corporation Ltd. (TNMSC) – the company responsible for all drug procurement on behalf of the Government of Tamil Nadu. The TNMSC warehouse confirmed that the drugs in question had in fact been acquired from Alfred Berg & Co.

112. On receiving a confirmation that Alfred Berg & Co was in fact the manufacturer, the Drug Inspector from Gudiyattam teamed up with the Drug Inspector of the district where the Alfred Berg & Co factory was located and together conducted a joint inspection of the company's manufacturing plant. A showcause notice was served on the company along with a request to submit particulars like batch manufacturing records, analytical report of raw materials, purchase details, analytical reports of the finished product, raw material register, packing material register, purchase details of raw materials etc.

113. The joint-inspection was carried out on January 8, 2014. During the investigation, the drug inspectors discovered shocking lapses in following good manufacturing practices, especially in maintaining proper records of manufacturing and quality control process. The Batch Manufacturing Records showed that there was a long gap of around 12 days between granulation and compression and surmised that the long gap possibly led to the mix up in labelling the drugs. The inspectors also noted that the records did not contain in-process details such as hardness test, thickness test, friability test and disintegration test. Similarly, the inspectors noted that the company had analysed only the finished tablet and not the final product (i.e. after the tablet has been packaged). With respect to the GMPs, the drug inspectors noted that the “whole premises is congested with ready for compression granules, compressed tablets, packing materials and raw material without any proper labelling and strips of final packing of Glibenclamide four batches were

kept together without any demarcation.” It was also discovered that the company did no stability testing on this product.

114. As far as the company's record keeping is concerned, the drug inspectors noted that the company did not maintain required records and registers as per Schedule U of the Drugs & Cosmetics Act and that it appeared that the company was simply manufacturing the drug first and was creating records thereafter. In particular, it was noted that the “Records of Raw Materials” were not maintained properly. The inspectors also opined that “the manufacturer did not produce the proper and genuine records to investigate and inspection to cover their mistakes’.

115. The complaint then makes the explosive allegation that the mislabelling of Glibenclamide for Glipizide was done on purpose for profit purposes since the former was priced at only Rs. 1900 per kg while the latter was priced at a much higher Rs. 9000 per kg. This allegation is supported by the fact that the company hadn't

maintained proper Records of Raw Materials – a document which would have helped the inspectors conclusively determine whether the mix-up was deliberate or a genuine error. When bank details and purchase details for raw materials were requested for by the drug inspector, the company claimed that it didn't maintain such records at its factory site and that such records were maintained at its head office and requested more time – a subsequent reply from the company reportedly noted that the company did not maintain a stock register or packing material register for the year 2012-13.

116. In order to estimate the scale of profits made by the company it may help to assess the number of tablets sold by the company: the company had reportedly manufactured 5,75,400 tablets and released 5,67,000 tablets for sale. Of these 1,57,000 tablets were sold to the TNMSC warehouse in Vellore, while 2,60,000 + 1,50,000 tablets were sold to the TNMSC warehouse in Kanchipuram. As you can see, in addition to the risk to patients, the

public exchequer has been defrauded by such sales.

117. Ultimately, the drug inspectors decided to charge Alfred Berg & Co. along with its directors and quality control staff with the following offences:

(i) Section 18(a) (i) read with Section 17B (d) of the said Act for having manufactured for sale and sold a “spurious drug”;

(ii) Section 18(c) read with Rule 74(c) for failing to completely test the finished product of the said batch of subject drug which is punishable under Section 27(d) of the said Act;

(iii) Section 18(c) read with Rule 74(d) for having failed to maintain the required records and registers as per Schedule of the Drugs and Cosmetics act, 1940 which is punishable under Section 27(d) of the said Act.

118. This case is one of the rare prosecutions that we could obtain which specifically charges the accused with failing to maintain records as required by the GMPs outlined in Schedule M & Schedule U of the Drugs & Cosmetics Act. Most importantly, the TNMSC [blacklisted Alfred Berg & Co](#) for

all tenders till March, 2019. It is very likely however that the blacklist was applied only toward the purchase of this drug because we discovered that Alfred Berg & Co. was listed on earlier blacklists by the TNMSC when it made the current sale to TNMSC.

119. [Drug Inspector, State of TN v. Res Sancta & Others.](#) **Before the Judicial Magistrate Court, Tiruvannamalai-I:** This case was relatively simple compared to the one above. The Drug Inspector had drawn a sample of Dolocold Suspension 60 ml from a pharmacy in Vellore district and sent the sample for testing on August 16, 2013 to the Drugs Testing Laboratory, Tamil Nadu. The test report from the government lab was returned on March 20, 2014 – a full 7 months later – declaring the sample to be NSQ because the content of Phenylephrine Hydrochloride in the sample was only 27.82% of what was declared on the label. Dolocold suspension is [reportedly](#) a Fixed-Dose-Combination of Paracetamol (125 mg), Phenylephrine (2.5 mg) and Chlorpheniramine Maleate (1 mg). The [list of indications](#) for this FDC include everything from allergies, cold,

ear pain, fever, flu, hay fever, headache, joint-pain, nasal decongestant, toothache, runny nose.

120. Although, the brand name appears to be owned by Micro Labs Ltd., the manufacturer of the drug in this case was Res Sancta, a partnership firm based in Solan – Himachal Pradesh. The Drug Inspector was able to establish the supply chain from the pharmacy to the manufacturer without much difficulty.
121. Subsequent investigation in this case wasn't as detailed as the previous case; perhaps because the manufacturer was more co-operative. In its defence, the manufacturer tried arguing that the control sample it retained was tested and found to comply with standards but the complaint noted that no documentary evidence was submitted in support of this evidence. Other defences proffered by the manufacturer were similarly dismissed by the drug inspector. Ultimately a prosecution was launched against the manufacturer and all the partners were charged under Section 18(a) (i) and Section 27(d) of the said Act.

122. **Other investigations:** In addition to the above prosecutions, there are several other cases (available here: [1](#), [2](#), [3](#), [4](#) & [5](#)) where investigations into NSQ drugs haven't always resulted in prosecution of the manufacturer because most drug controllers follow a set of Guidelines laid down by the DCC which recommends prosecutions only in the most serious cases. Even when the drug inspector establishes culpability with the help of the government laboratory when the sample fails the quality parameters laid down in the pharmacopeia, no prosecution is initiated. In such cases, the drug inspectors in Tamil Nadu recommend that they be referred to either to the state where the manufacturer is located or alternatively suspend the licence for a brief period of time.

123. **A summary of the problems faced in the investigations under the Drugs & Cosmetics Act: co-ordination, investigation tactics, GMP compliance:**

(a) Jurisdiction problems & Lack of co-ordination: One of the main problems with most of the

investigations discussed above is that there is very little coordination between drug inspectors within the same state or between different states and also between the drugs inspectors at the state and centre. Such co-ordination is of paramount importance to create an effective regulatory framework because the drug inspector who draws the sample and who is responsible for prosecution often does not have the jurisdiction to raid the premises of the manufacturer or suspend the manufacturing licence of the offending manufacturer;

(b) Lack of thorough investigations:

As seen in most cases, discussed above, state drug inspectors do not appear to be inspecting various records and registers that are required to be maintained as a part of the Good Manufacturing Practices (GMPs). An inspection of these records and registers is necessary to build a strong case about the extent of negligence or recklessness by the manufacturer during the manufacturing process or quality control. Similarly, it should be

mandatory for the inspectors to seize and test the batch reference samples that are required to be stored by each manufacturer. Such testing is required to deflect a possible defence by the manufacturer that the drug tested as NSQ because of poor storage either at the pharmacy or in the transport vehicle. Last, but not least, since most records are now computerised, and the GMP standards in schedule M have specific requirements to ensure that computerised records are not manipulated, it is necessary for drug inspectors to be accompanied by software specialists who are capable of conducting forensic audits. Such audits are required because foreign regulators like the USFDA have detected several cases where Indian manufacturers have manipulated digital records in order to hide manipulation of records to mask quality issues with a particular batch.

(c) Only punitive & not remedial: The focus of almost all the investigations that we

studied for this report were aimed at prosecuting the manufacturer for the act of selling the NSQ drug. There is however little effort to ensure that the investigation actually identifies all defects in the manufacturing process so that the manufacturer takes remedial action to avoid repetition of the same problems. Criminal justice processes in other jurisdictions like the United States require the offending manufacturer to become a signatory to what is called a Consent Decree and Corporate Integrity Agreement. The goal of such agreements is to ensure that the manufacturer doesn't lapse into the same behaviour that resulted in the manufacture of NSQ drugs in the first place. Ideally, the manufacturer should not even be allowed to manufacture until all defects are remedied, which is how the US FDA treats offending manufacturers. 44 pharmaceutical manufacturing facilities in India have been banned from exporting their product to the United States.

(e) Lack of surprise search and seizure raids on the manufacturer's premises: Despite the Drugs & Cosmetics Act empowering drug inspectors to conduct searches of manufacturing premises under Section 22,

it appears that drug inspectors never exercise these powers. While one possible reason for not exercising such powers is likely because of jurisdictional issues; the inspector who seizes the sample of the drug will only rarely have jurisdiction over the manufacturing plants. Another likely reason for the failure to use these provisions more frequently is because of Section 34AA, which is a vaguely worded provision that imposes a fine on drug inspectors for vexatious searches.

(f) Dealing with claims of spurious drugs:

One of the major problems in the investigation process is the lack of set protocols dealing with drug manufacturers who disavow a sub-standard product bearing their name by claiming it to be spurious or counterfeit. This defence is usually taken in cases where the pharmacist has failed to maintain purchase records thereby making it difficult to establish the supply chain custody back to the manufacturer. Drug Inspectors should be provided with a proper protocol on exactly how to examine such claims pertaining to NSQ drugs. For instance, batch manufacturing records and sales records should be examined in detail. The task of certifying

whether the product is in fact spurious or NSQ should not be left to the manufacturer because it provides an easy way out for offending NSQ manufacturers and evade prosecution.

(e) Vicarious liability of the trademark owner in case the contract manufacturer produces NSQ drugs:

One of the problems with cases of contract manufacturing, where the manufacturing is done by one company and sold under the trademark of a different company, is that the trademark owner is usually not charged in case the drug is detected to be sub-standard. For example, the cases above against Akum Pharmaceuticals and Perennial Medicare, the drugs in question were being sold under trademarks owned by other companies but in neither case did the drug inspector name the trademark owners in the criminal complaint that was eventually filed against the manufacturer. The failure to name the trademark owner defies logic because most patients are likely to buy a particular drug based on the trademark and since the trademark owners profit from the sale of drug product, they should be charged with criminal liability for the sale of sub-

standard medicine. Section 27 of the Drugs & Cosmetics Act, 1940 provides for such vicarious criminal liability to be foisted on the trademark owner because the provision states “Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes.” Thus, in cases where a pharmaceutical company manufactures a drug on behalf of the trademark owner, the trademark owner should be held accountable and charged with the same offences as the manufacturer.

(f) Charging for offences under Section 27(a): A recurring problem in each and every criminal complaint that we perused was the failure to charge the accused under the proper provision of the Drugs & Cosmetics Act. The default approach in all of these complaints pertaining to sub-standard drugs was to charge the manufacturer under S. 27(d); this is basically a residuary provision in Section 27 which provides for penalties for offences not specifically defined in the other provisions of Section 27. However such an approach is not correct. A careful reading of Section 27(a) will demonstrate that the provision applies to

any drug which may cause grievous hurt to the patient consuming a drug. The relevant wording of the provision is reproduced below:

*(a) any drug deemed to be adulterated under section 17A or spurious under section 17B or **which when used by any person** for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or **not of standard quality, as the case may be,** shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;] (Emphasis added)*

Therefore, if the nature of the defect in a sub-standard drug has the effect of causing “grievous hurt” to a patient consuming such drug, the manufacturer and seller can be charged under S.27 (a). The key difference between S. 27(a) and 27(d) is that the former provides for a minimum punishment of five years and a maximum of ten years while the latter

provides for a minimum punishment of one year and a maximum punishment of two years. The deterrent under S. 27(a) is therefore much higher. In order to examine whether S.27 (a) is applicable to the facts of a case, it is necessary for the drug inspector to get a medical opinion on the effects of a particular defect in a drug. However due to the convoluted wording of the provision, it appears that most drug inspectors will invoke S. 27(a) only in cases of spurious or adulterated drugs and not in the case of sub-standard drugs. And the data shows, India has a problem with sub-standard drugs, not spurious drugs.

(g) Training drug inspectors: Most of the problems that we've identified above can be remedied only through better training of drug inspectors and by the appointment of specialised prosecutors who are trained to effectively prosecute these cases before courts of law.

Section E: Confusion in different states regarding courts with appropriate jurisdiction to prosecute offences under the Drugs & Cosmetics Act, 1940

124. As per Section 32 of the D&C Act, all criminal prosecutions under Chapter IV of the D&C Act, no court inferior to that

of a Court of Sessions should try any offences unless otherwise provided in the Act. There is however significant confusion amongst different states on whether a Court of Sessions can directly try such offences. In order to understand the problem, it is necessary to understand the manner in which the law has been amended over the last seventy years.

125. As originally enacted in 1940, offences under the Drugs & Cosmetics Act could not be heard by any court inferior to that of a "Presidency Magistrate or of a Magistrate of First Class". In 1982, the law was amended to replace the earlier phrase with "Metropolitan Magistrate or of a Judicial Magistrate of the first class". In 2008 this was further amended as follows "(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter". The amendment in 2008 shifting the jurisdiction for offences under Chapter IV from the Judicial Magistrate First Class (JMFC) to the Court of Sessions, signalled the intention of Parliament to treat such offences as grave offences requiring the attention of more experienced judges.

Additionally, it should also be noted that Session Judges are generally thought to have a lesser case-load than magistrates meaning that such cases would progress through the system much faster.

126. Unfortunately, there appears to be a fair degree of confusion amongst High Courts and Drug Inspectors in various states on handling of such cases. For example, the Kerala High Court in the case of *Zest Pharma M.P. v. Drugs Inspector* 2013 (4) KLT 462, held that “even now after the amendment of 2008, the Magistrate’s Courts are vested with the jurisdiction and power to try the offences under Section 18(a) (i) read with Section 27(d), if the allegation under Section 18(a) (i) is that the drug is ‘not of a standard quality’”. The Court came to this reasoning based on a rather confusing interpretation of S.36AB of the Act. However the Karnataka High Court in the case of *Deepesh Arvindhbhai Patel & Ors. v. State of Karnataka* MANU/KA/0747/2015 has held the

opposite. Referring to Section 32, the Hon’ble High Court held “On plain and meaningful understanding of the

provision, the offences which are recognized under Chapter IV of the Act, are made punishable and triable by the Court of Sessions. Section 32(2) of the Act clearly discloses that - Save as otherwise provided under this Act, no Court inferior to the Court of Sessions, shall try an offence under Chapter IV starting from Section 16 to 33A of the Act. Section 17 and 18 are covered under this particular Chapter. Therefore, the learned Sessions Judge will get powers to take cognizance and try the said offences. Therefore, in my opinion, there is no jurisdictional error committed by the learned Sessions Judge in taking cognizance and issuing summons.” In a judgment by the Patna High Court in the case of *Rabindra Singh v. State of Bihar* 2015 Cri LJ 471 it was held that the wording of Section 32 indicated that the Session Court could only ‘try’ the offence and not take cognizance of the offence. According to the Hon’ble Court, the provisions of the Cr.P.C. would continue to operate in such a scenario. Thus only a Magistrate could take cognizance of the offence and thereafter commit the case to the Sessions Judge under the provisions of Section 209 of the Cr.P.C.

127. As can be seen from above, there is a significant divergence between three High Courts when reviewing this matter. While the Kerala High Court states that JMFCs can continue to try cases of NSQ, the Karnataka High Court is quite categorical in its conclusion that a Sessions Judge can take cognisance and also try such cases. The Patna High Court however is quite clear that a Sessions Judge can try such cases only after a committal from a JMFC who has taken cognisance of the complaint.

128. Given the level of divergence amongst the various courts, it is necessary for the Supreme Court to rule on the issue or alternatively, for the government to step in and amend the provision.

Section F: The lack of enforcement of minimum mandatory prison sentences by the judiciary;

129. Given the grave consequences posed to public health due to the consumption of NSQ drugs, the D&C Act mandates certain minimum term of imprisonment which have to be adhered to by all judges during sentencing except in certain cases

where judges may sentence a person for 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.

130. In reality, most courts appear to be invoking the exception more often than the rule by sentencing persons found guilty of manufacturing NSQ drugs to 'simple imprisonment till the rising of the court'; i.e., the accused is convicted but is not actually sent to jail – instead he is required to be in court till the judge rises from the court for the day. Once the judge rises from court, the convicted person is deemed to have served his time and is allowed to leave.

131. During the course of our research, we procured a 'List of Convictions' from the Karnataka Drugs Control Department (KDCD) which recorded the convictions and punishments in prosecutions launched by the Department between 2011 and 2015. This list covered all convictions under the Drugs & Cosmetics Act (not just NSQ), Drug Price Control Order (DPCO). Except for one of the cases, we noticed that in every other case, the criminal courts were imposing only small monetary fines ranging from Rs. 5000 to Rs. 1 lakh. With regard to imprisonment, judges were imposing a lenient sentence of simple imprisonment till the rising of the court,

which basically means the person is deemed to have served his sentence once the court rises for the day. Only in one case in the five year period, was the convicted person sentenced to a prison term for a period of one year. This trend is surprising because several offences under the Drugs & Cosmetics Act (including the manufacture of NSQ drugs) a minimum mandatory prison term of one year is prescribed by the law. How then were judges passing sentences of simple imprisonment till the rising of court?

132. In order to understand this issue we procured 6 judgments passed by the Special Court for Economic Offences in Bangalore where, despite guilty pleas by the accused, all of them were sentenced only with simple imprisonment till the rising of the court. The judge did not impose the minimum imprisonment of one year even in even one of these cases. The monetary fines imposed in all of these cases ranged from a minimum of Rs. 5000 to a maximum of Rs. 35,000. In most cases, the Court awards this lenient sentence on the grounds that the accused had family dependant on his earnings.

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. Injecto Capta Pvt. 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
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;

133. In all of the above judgments, the Court justifies this lenient punishment with the reasoning that the charge against the accused was one of selling drugs which are not of standard quality, as opposed to the more serious offence of selling counterfeit medicine. This points to the effective campaign by the industry on reducing the impact of NSQ drugs which are a much bigger problem than counterfeit medicine, i.e., spurious drugs in India. The court fails to understand that in several cases, sub-standard medicine can have similar effects as counterfeit drugs. For example, if a drug fails to dissolve or disintegrate it will have no effect on the human body. Depending on the drug in question, the lack of such action can have serious consequences on a patient. It is therefore necessary for courts to seek an expert opinion from pharmacologists or medical doctors on the effect of the sub-standard medicine before deciding to let the accused off with simple imprisonment till the rising of court.

134. Further, the Supreme Court has been very clear that mandatory minimums need to be enforced strictly against accused. The Supreme Court has [time and again ruled](#), in the context of different laws that the 'special reasons' exception can be used only in exceptional cases and not ***in a routine, casual and cavalier manner***.¹⁴ However given the weak prosecutions it is no surprise that the government is not pushing for the minimum mandatory imprisonments in all cases of sub-standard drugs. Due to this anomalous situation, manufacturers under the Drugs & Cosmetics Act get away with little or no punishment.

Section G: The suspension and cancellation of manufacturing licences

135. In addition to the process of criminal prosecution to punish violators of the D&C Act, the Drugs & Cosmetics Rules, 1945 also provide for suspending or cancelling the manufacturing licences of the company found to have manufactured NSQ drugs. As explained above, according to the DCC

¹⁴ State of Rajasthan v. Vinod Kumar (Criminal Appeal No. 1887 of 2008)

Guidelines for Prosecutions, drug inspectors have been advised to opt for suspension/cancellation of licences in most NSQ cases, rather than opt for criminal prosecution. Given that suspensions/cancellations are the preferred mode of enforcement in India, it is necessary to understand how this system actually works in practice.

136. The relevant rule in this regard is Rule 85(2) of the Drugs & Cosmetics Rules, 1945. *(2) The Licensing Authority may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reason therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, [or direct the licensee to stop manufacture, sale or distribution of the said drugs and an Inspector] if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or Rules thereunder.*

137. This power is exercised by Drug Controllers in individual states, since it is State Governments and not the Central Government who licence drug manufacturing in India. This Rule states that the licensing authority may, after giving the licensee an opportunity to show cause, cancel a licence issued or suspend it for such period as he thinks fit either for the facility or for manufacture of a specific drug.

138. The problem with this provision is that since each State Licensing Authority (SLA) operates independently of the others, there is no uniformity in the duration for which licences are suspended or cancelled. We have near certain information of this practice from copies of the Register of NSQ drugs maintained by the Karnataka Drugs Control Department (KDCD) that we procured under the Right to Information Act, 2005. This Register contains details of all the NSQ drugs detected by the KDCD within the state of Karnataka and the action taken against them by their respective drug controllers. 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. In such cases, the Drug Inspectors from Karnataka wrote to their counterparts in the other states and requested them for action to be taken against the offending manufacturers located in those states. The drug inspector in the home state of the offending manufacturer would then write back to the Karnataka Drug Inspector informing them of any action taken against the manufacturer in terms of either suspension or cancellation of licensees. The action taken by these other SLAs would be jotted down in the register in a hand-written format.

139. 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 of erring manufacturers 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. This large scale discrepancy in the duration for which licences are suspended in different states is because there are no rules notified by the Ministry of Health and Family Welfare 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.

140. A second and more serious issue with the practice of suspending licences is whether SLAs actually enforce their orders suspending manufacturing licences. Typically if these suspension orders were being aggressively enforced, one would expect to find several cases in the High Courts by pharmaceutical companies challenging the suspension orders and seeking stay orders. However a search of the reported judgments of the High Court for the state of Himachal Pradesh (the biggest source of NSQ drugs) did not reveal a single judgment where the issue of a suspended licence was challenged in the High Court. Given how combative the industry is when it comes to any punitive action affecting their profits, it is strange that none of the

suspensions have ever been challenged before the High Courts. This calls into question the effectiveness of SLAs in enforcing their own suspension orders.

Part III – The absence of fundamental quality testing and recall norms in Indian law

141. Any regulatory debate has two specific aspects. The first aspect is whether the regulatory system is governed by appropriate laws and policies and the second aspect focuses on enforcement of the law and policies on the ground. The drug regulatory debate in India over the last few years has concentrated on whether Indian drug manufacturers are meeting the requirements laid down by American and European law while exporting drugs to those jurisdictions. There has been virtually no public debate on whether Indian laws are prescribing standards equivalent to those in the United States or the EU. It is important to examine this aspect because a closer examination demonstrates that Indian citizens are being treated as second class citizens by its own pharmaceutical industry. For instance, while Indian

manufacturers exporting to the US and EU have to mandatorily conduct bioequivalence and stability tests to prove that their product are indeed therapeutic and effective until the expiration date, Indian laws do not require such tests to be conducted for drugs sold to Indian patients. Similarly, while foreign jurisdictions like the US and EU have robust mandatory drug recall mechanisms and Indian pharmaceutical companies regularly conduct recalls of their products in the US and the EU, there is no similar requirement in the law in India. As a result, even after drug controllers determine that a particular batch of drug is unsafe or NSQ, there is no requirement under the law to withdraw that particular drug from the market. These issues and the dangerous public health consequences of these various shortfalls are explained below in more detail.

Section A: The lack of mandatory bioequivalence testing under the Drugs & Cosmetics Rules & its consequences for public health;

142. The Drugs & Cosmetics Act, 1940 which is the main legislation responsible for regulating the quality of Indian drugs has created a two-tiered system. The central regulator grants approvals for a 'new drug', while state level regulators licence manufacture of drugs of new drugs. A 'new drug' as defined in Indian law, is any drug which has not been recognised as safe and effective in India and is approved after the regulator analyses all safety data.¹⁵ Such a drug will maintain its 'new drug' status for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.¹⁶ Within this four year period, depending on the patent status of the drug, multiple pharmaceutical companies may seek the central regulator's approval to manufacture the generic version of the drug. After the four year period expires, any pharmaceutical company seeking to

manufacture a generic version of the new drug, is required to approach only a state regulator for procuring a manufacturing licence. Such licences are supposed to be granted by the state authorities after ensuring compliance of the manufacturing plant with all requirements of Indian law, including GMPs.

143. Strangely enough Indian law prescribes different criteria for generics which are classified as 'new drug' (approved only by the central regulator) and generics which are not classified as 'new drug' any longer (approvals granted by the 36 different state regulators). In specific, generic drugs in the 'new drug' criteria are required to be bioequivalent to the innovator product and are also required by law to establish their stability.¹⁷ However, for generic drugs, after the expiry of the 4 year period of the new drugs status, there is no mandatory requirement for either bioequivalence or stability studies. The reason for this divergence is not clear.

¹⁵ Rule 122-E of the Drugs & Cosmetics Rules, 1945

¹⁶ Explanation to Rule 122-E of the Drugs & Cosmetics Rules, 1945

¹⁷ Schedule Y – Appendix 1 & Appendix 1A to the Drugs & Cosmetics Rules, 1945

144. The importance of bioequivalence studies & its implication for public health: The thalidomide tragedy in Europe in the 1960s was one of the defining moments of the modern pharmaceutical industry. The tragedy, led to the introduction of a legal framework which mandated rigorous clinical trials, wherein a new drug would be tested on human patients before being approved for clinical use. The clinical trials mandated post the thalidomide tragedy are expensive, risky affairs. Legislation like the Hatch-Waxman Act, enacted in the US in 1984, created a new regulatory pathway which allowed generics to enter the market if the regulator was satisfied that the generic drug was bioequivalent to the innovator product. There was no requirement for the generic to repeat expensive clinical trials in order to get approvals. Unlike clinical trials which are carried out on a patient population, a bioequivalence study is carried out on a very small number of healthy subjects and is therefore significantly cheaper and safer when compared to a full scale clinical trial.

145. The object of a bioequivalence study is to establish that the generic drug has the same rate and extent of absorption, in the human body, as the innovator drug product. The science behind a bioequivalence study is relatively simple. All drugs have what is called the API, the active ingredient which cures the ailment along with other filler material called excipients. The way the API and excipients come together to form the dosage (e.g., a tablet, or capsule or a syrup or an injection) requires a special process, which is based on established science. Parameters like particle size, blend uniformity, tablet weight, breaking strength, density, flow property, punch penetration etc. all have a material impact on how fast the dosage dissolves (established by a dissolution test), absorbed into human body and becomes therapeutic. Conducting a BE study evaluates how a particular formulation behaves in the bloodstream of a human being when compared to the innovator drug it copies demonstrating whether the intended therapeutic effects can be reasonably guaranteed in human physiology.

146. If a generic drug fails a BE study, it means that it doesn't behave in a manner similar to the innovator drug. This is not necessarily bad in itself. The innovator drug has very specific characteristics, called the Pharmacokinetic (PK) and Pharmacodynamic (PD) profile that shows how it behaves in the human body. If the generic formulation fails the BE study, it means that its method of action is different from that of the innovator drug it intends to copy. The science behind the innovator drug and its therapeutic effect is established by the innovator company through clinical trials. Therefore, if the generic drug behaves differently, it means that the regulator then has to evaluate whether the generic formulation has the same therapeutic effect, side effects and overall characteristics as the innovator drug does. This requires a clinical study. The route of approval for such a product is different and is not governed by the regulations that accord approval for generic drugs. If however, a BE study is not conducted, there is absolutely no way to verify the manufacturer's claim that its drug

works at all, let alone work as well as the innovator's drug.

147. The generic pharmaceutical industry in India, in conjunction with Indian clinical research organisations (CROs) have a long history of manipulating bioequivalence studies required by the American and European regulators. The Ranbaxy scandal, which first came to light in 2003, exposed the scale of fabrication and manipulation of bioequivalence studies being conducted in India. Recent investigations by the French regulator ANSM at GVK Bio, by the USFDA at Semler Research and the German regulator at Alkem Laboratories have exposed how Indian CROs continue to manipulate bioequivalence studies for their clients – mostly the Indian industry.

148. Recommendations by Indian authorities to make Bioequivalence and Stability testing mandatory for all generics: In July, 2013, an expert committee headed by Dr. Ranjit Roy Chaudhury constituted by the Government of India to formulate a new policy on drug approvals and clinical trials had recommended that bioequivalence (BE) studies be made

compulsory for both 'first time generics' and also 'subsequent generics'.¹⁸ However in cases of highly soluble molecules, the Committee had recommended waiving the requirement to carry out such BE studies, as is also done in the US.

149. This report by the expert committee was discussed by the Government of India's Ministry of Health & Family Welfare. In a report discussing the Committee's recommendations, the Ministry stated that it would seek wider consultations with stakeholders since the recommendation to make BE studies compulsory would have a cost impact on drugs. The Ministry noted: "Presently, BE study for oral dosage form of only new drugs is required till four years of approvals of these drugs. In order to make it mandatory for all drugs other than new drugs, it would require amendment in Rules. Such a provision will have an impact on cost, time required for grant of

license, infrastructure etc. Hence, this Ministry will seek wider consultation with the stakeholders on this recommendation."¹⁹

150. Thereafter, this recommendation was discussed at the 47th meeting of the Drugs Consultative Committee (DCC) held in July, 2014. The DCC is a statutory committee consisting of representatives of all the central and state drug controllers, along with representatives of the Government of India. In this meeting the DCC discussed the Expert Committee's recommendation and rejected the same on the grounds that India lacked the infrastructure to carry out such studies. The exact reasoning of the DCC is reproduced below:

"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

¹⁸ Report of the Prof. Ranjit Roy Chaudhary Expert Committee to Formulate Policy and Guidelines for Approval of New Drugs, Clinical Trials and Banning of Drugs at p. 38, 39. (July 2013)

¹⁹ Actions on the recommendations of Prof. Ranjit Roy Chaudhary Expert Committee to formulate policy and

guidelines for approval of new drugs, clinical trials and banning of drugs, MOHFW available at <http://www.mohfw.nic.in/WriteReadData/1892s/6530718705Ranjit.pdf>

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."²⁰ In the same breath however, the Committee recommends that BE studies be conducted for the purposes of export consignments if foreign countries so required such approvals. Apart from the hypocrisy of placing the patients of developed countries on a higher plane than Indian patients, it is also factually incorrect that India lacks the infrastructure to carry out test because India has a thriving CRO industry, which conducts BE tests for both Indian and foreign companies.

Section B: The lack of mandatory stability testing under the Drugs & Cosmetics Rules

151. The difference in regulations for the drugs that are exported and those which are consumed by patients in India also extends to the issue of stability testing. The US & EU require rigorous

stability studies to be conducted on any drug being sold in their markets. 'Stability studies' are required to ensure that drugs do not breakdown due to atmospheric conditions such as temperature and humidity during their storage and that the drug is stable till the claimed date of expiry on the label. These studies are conducted by placing a sample of the drug in a controlled environment such as a refrigerator and subjecting it to differing atmospheric conditions to test whether the drug decomposes. Parameters for stability testing differ amongst different countries depending on their climate. Globally, most regulators recognise four zones, depending on their climate. These are Zone I (Temperate), Zone II (subtropical, with possible humidity), Zone III (hot/dry) and Zone IV (hot/humid). India falls in Zone IV.

152. Stability testing is of paramount importance in a country like India because of our hot and sometimes humid climate which creates conditions conducive to their degradation. A drug which fails stability

²⁰ Report of the 47th Meeting of the Drugs Consultative Committee held on 30th and 31st July, 2014 at New Delhi at p. 8-10.

testing will not have the same effect on patient as a stable drug. In the worst case, the products of the drug's degradation can lead to serious adverse effects. In either case, public health will be significantly compromised. The DCC, in a meeting in its 46th meeting held in November, 2013 had concluded that the lack of mandatory stability testing for generics licensed by SLAs was a 'serious lacuna' in the law.²¹ The Committee had unanimously recommended that the Drugs & Cosmetics Rules, 1945 be amended to make stability testing mandatory for all generic drugs, not just those which are in the 'new drug' category.²² However the rules have not been amended since; almost two and half years post the committee's recommendation.

Section C: The lack of a mandatory recall mechanism in Indian law;

153. One of the most significant failings of the Indian drug regulatory system is its failure to put in place a mechanism to recall NSQ drugs from the market. Such

recalls may be necessitated either by post-marketing surveillance or alternatively due to internal review of manufacturing processes within the pharmaceutical companies. For example, statistical quality control on a series of batch records may indicate trends which are not easily recognizable from a single batch record. Likewise, long term stability studies may reveal that a particular batch degrades quicker than what is printed on the label. In such cases, a robust and traceable process to account for all commercial product present in the market so that it can be returned and destroyed is a key component of the regulatory oversight.

154. Indian pharma companies regularly conduct drug recalls in the US and EU. In the recent past, there have been several cases of large pharmaceutical companies like Sun Pharma, Dr. Reddy's and Wockhardt recalling, hundreds if not thousands of units of their drugs from the American market. However, similar drug recalls are almost never affected in the Indian market.

²¹ Report of the 46th Meeting of the Drugs Consultative Committee held on 12th and 13th November, 2013 at the Hotel Metropolitan New Delhi – 110001 at p. 28.

²² *Id.*

This is because the Indian drug regulatory law does not have a legal framework mandating such recalls. Every time a drug is declared NSQ by a government analyst, there is no legal requirement under the law for the manufacturer to initiate a nation-wide recall and there is no procedure to monitor such recalls. The futility of the Indian system was pointed out in the 59th Standing Committee report when it noted:

“15.5 By the time a sample is tested, a large number of packs get sold out with undeterminable injury to patients. There is no effective method of recalling unsold stocks lying in the distribution network. This cannot be allowed to go on.”

155. At the time of the 59th report, the Committee was pushing for more transparency in informing the public about the presence of NSQ drugs – in particular, it wanted publication of the NSQ drugs in newspapers. The relevant paragraphs are extracted below:

“15.11 The Committee recommends that once a batch of a drug is found to be

substandard and reported to CDSCO, it should issue a press release forthwith and even insert paid advertisements in the newspapers apart from uploading the information on the CDSCO website. Retail chemists should be advised to stop selling unsold stocks and return the same to local Drugs Inspectors as per rules. The Committee understands that at least two State Drug Authorities that of Maharashtra and Kerala, have taken the initiative to upload information on spurious and sub-standard drugs on their websites on a monthly basis. These are welcome measures worth emulating by other states and the Centre.”

156. The Committee's singular focus on this issue helped in creating the current 'Drug alert' system wherein the CDSCO publishes information on its website about drugs declared NSQ in central government laboratories. Such a system is really useless unless integrated with the state government labs, since the states are the ones which conduct a lion's share of testing. The Standing

Committee was very cognizant of these limitations, especially the consequence of only the CDSCO making information available on its websites. In its 66th report had pertinently stated:

“3.195 The Committee notes that to begin with CDSCO has started the drug alert system in respect of drugs found to be not of standard quality, spurious, adulterated, etc. by central drug testing laboratories. Furthermore, the Ministry is considering the feasibility of placing advertisements of such cases regularly in the newspapers. The Committee is convinced that this is a herculean task, which can be achieved only when the efforts of the Centre and State Governments are fully synergized. Drug alerts of evaluations by central drug laboratories though welcome would not take care of this acute problem in entirety as the state drug laboratories handle major volumes of such evaluations. The Committee, therefore, desires the Ministry to take up this matter with State

Governments on a highly proactive basis to ensure its early fructification. It also desires early decision by the Ministry on utilizing newspapers in this task.”

157. Currently, some state regulators from states like Gujarat and Maharashtra do make available the most recent NSQ data on the XLN website. Very few people, even within the industry, know of this website. Some other state regulators do send such information to newspapers which publish the information in small columns in their city editions, but this information is of little use given the level of inter-state commerce of drugs in India; a batch declared NSQ in Maharashtra may have also been partially sold to other states. The only way to fix this system is to have a nationwide recall system implemented and monitored rigorously by the CDSCO. In quite a coincidence, at about the same time that the 59th Report pointed out this issue to the government, the World Health Organisation (WHO) had raised the same red flag during its National Regulatory Assessment (NRA) of the CDSCO. As a result the CDSCO published for the very first time Draft

Guidelines on Recall of Drugs. While some news websites reported that the Guidelines are now in effect, we have not found any evidence to substantiate this claim. These draft guidelines were published on the internet for comments and were subsequently discussed at the 45th and 46th meetings of the Drugs Consultative Committee (DCC), held in February, 2013 and November, 2013. However, neither the public information officers in the CDSCO nor the state drug regulators seem to be aware of these guidelines when we filed RTI applications with each of these authorities asking them whether they follow any particular recall guidelines.

158. In a RTI application filed on April 15, 2015 we asked the CDSCO the following questions:

“(i) Does the CDSCO have in place a mechanism to issue a safety alert or a product recall on the basis of a test report from a State Drug Controller which indicates that a product is not of standard quality?

(ii) Please provide copies of all such orders issuing safety alerts or product recalls in the last 2 years.

(iii) Are State Drug Controllers mandated to intimate the CDSCO

every time they detect a drug which is not of standard quality? Please provide all such intimations received by the CDSCO in the last 2 years.”

159. The reply we received from the CDSCO places the entire responsibility of recalls at the doorstep of the state regulators. The reply does not even mention that draft guidelines have been drafted by the government.

160. In June 2015, we filed a second set of RTI applications where we asked the CDSCO the following question:

“(i) Please provide the applicant with a copy of the guidelines or rules laid down by the CDSCO in order to issue “Drug Alerts” or “Recalls”.

161. The response was completely silent on the guidelines and speaks only of drug alerts.

162. We then repeated this exercise with a series of state drug regulators asking them the following two questions:

“(1) Does the Controller follow any specific rules or guidelines to recall a drug that is detected as being of ‘Not of Standard Quality’. Please provide the applicant with a copy of such rules of guidelines.

(2) 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."

163. Each of the responses from Maharashtra, Andhra Pradesh, Tamil Nadu, Karnataka, Uttarakhand & Himachal Pradesh contained a different answer – while HP and Karnataka refer to the DCC Guidelines on prosecution, others like Maharashtra claim that recalls are governed by the Drugs & Cosmetics Act – both answers are wrong. The DCC guidelines don't mention anything about drug recall and the D&C Act doesn't deal with drug recalls. The authority in Tamil Nadu responded claiming that recalls were dealt with under Schedule M to the D&C Act – this schedule contains the GMP code, under which all

manufacturers are required to have a recall system in place but such a system is very different from a mandatory drug recall system where a regulator supervises a nation-wide recall. Other countries like the USA, the UK, have a specific legal framework to govern such recalls. The only state which appears to have a rudimentary system in place is Andhra Pradesh. That state regulatory agency has some rules that mandate information sharing with all drug inspectors. However state-wise regulatory mechanisms are completely useless in India since drugs can flow across borders seamlessly – the only solution is a centralised recall procedure.

164. The enactment of a mandatory recall mechanism will be a game-changer in the Indian context not only because unsafe drugs would be withdrawn from the market but also the number of alerts generated by each state would have forced a wider debate on the reason behind such recalls. The biggest challenge we face in addressing this problem of substandard drugs is public awareness about their prevalence and

outcomes from their use. A wider national debate about consolidated recalls across states would have raised this issue prominently in the media and public eye.

Part IV – The 59th Report of the Parliamentary Standing Committee on Health & Family Welfare on the functioning of the CDSCO

165. The 59th Report of the Department Related Parliamentary Standing Committee on Health & Family Welfare, which was tabled on the floor of Parliament in May, 2012 was a landmark event for drug regulation in India. This report conducted a thorough investigation of the regulatory practices followed by the CDSCO and exposed shocking practices following during the process of granting drug approvals. Given the prominence of parliamentary standing committees in the parliamentary process, the 59th report sparked of a much needed public debate on the working of the Indian drug regulatory. This report also forced the Government of India to begin the process of reworking some of the drug approvals processes and

relooking some of the statutory provisions. However the really controversial recommendations which would have had a significant impact on the drug regulation were either ignored or stonewalled by the Ministry of Health & Family Welfare. For example the Health Ministry has refused to investigate illegal drug approvals, despite the Katoch Committee Report (setup by the MOHFW to study the 59th Report) recommending investigations in all of the cases pointed out by the 59th Report. The Ministry had accepted the recommendations of the Katoch committee and had made written commitments to the Standing Committee stating that it would conduct such investigations. What is perhaps even more revealing is the fact that the MOHFW has declined to conduct such investigations even after the Standing Committee castigated the Ministry for the second time, in its 66th Report, for failing to follow up on the commitments made to the Committee after the tabling of the 59th Report.

166. In order to evaluate the degree of the Ministry's compliance with its own commitments to the Parliamentary Committee, given in writing in the Final 'Action Taken Report' (ATR) that was submitted to the Committee on December 28, 2012, we filed RTI applications with the Ministry. The important issues raised by the 59th Report and the Ministry's response to the same are discussed below in further detail.

Section A: Collusion and possible corruption in drug approvals

167. The most controversial and shocking findings of the 59th Report of the Parliamentary Standing Committee pertained to the manner in which drug approvals were being granted by the CDSCO. In particular, the Committee discovered likely collusion between pharmaceutical companies, doctors and CDSCO in the approval of certain controversial drugs. In several cases, the Committee discovered that drugs not approved anywhere else in the world were approved in India. When the Committee demanded investigations, the Ministry initially promised investigations but ultimately

never ordered any investigations. Some of these cases are discussed below.

168. Improper approval of Aceclofenac with Drotaverine: In its 59th Report, the Standing Committee had noted, with some concern, that several doctors sitting hundreds of kilometres away had given "identical" opinions to the CDSCO advising it to grant approvals for certain drugs. One such case was that of the fixed dose combination of Aceclofenac with Drotaverine where the committee noted 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. As a result, several of the expert opinions recommending the drug for the Indian market, were identical to each other, raising the Committee's suspicion that the doctors had simply signed the opinions prepared by the manufacturer. The Standing Committee thus demanded an investigation into the process by which CDSCO approved this drug

combination. In pertinent part, the Committee had noted the following:

“If the above cases are not enough to prove the apparent nexus that exists between drug manufacturers and many experts whose opinion matters so much in the decision making process at the CDSCO, nothing can be more outrageous than clinical trial approval given to the Fixed Dose Combination of aceclofenac with drotaverine which is not permitted in any developed country of North America, Europe or Australasia. In this case, vide his letter number 12-298/06-DC dated 12-2-2007, an official of CDSCO advised the manufacturer, Themis Medicare Ltd. not only to select experts but get their opinions and deliver them to the office of DCGI! No wonder that many experts gave letters of recommendation in identical language apparently drafted by the interested drug manufacturer....7.33 In the above case, the Ministry should direct DCGI to conduct an enquiry and

take appropriate action against the official(s) who gave authority to the interested party to select and obtain expert opinion and finally approved the drug.”

169. In its Final Action Taken Report (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 want only indulged in the above cited gross irregularity but also sufficed to take exemplary action against them so as to deter others. The Ministry by still dithering over issuing instructions to

NDACs and DCGI has abundantly proved that it has neither the intention to clean the Augean stables of CDSCO nor any concern for probity and rule of law. Hoping against hope, the Committee expects the Ministry to at least even at this late stage take immediate action on these proven cases of delinquency and irregularities so that a stern message is sent to all concerned that the drug regulatory mechanism is not up for grabs for perpetuation of unethical and illegal practices.”

170. We 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 on September 17, 2015 informing us that “no separate orders in this regard have been issued by the MOHFW”.

171. Improper Approval of Buclizine: Similarly, the Standing Committee in its 59th Report had noted that **Buclizine**, a drug that was originally brought to the market 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, Malaysia, 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 stated the following: “The Committee is of the view that responsibility needs to be fixed for unlawfully approving Buclizine, a drug of hardly any consequence to public health in India, more so since it is being administered to babies/children. At the same time the approval granted should be reviewed in the light of latest scientific evidence, regulatory status in developed countries, particularly in Belgium, the country of its origin.”

172. 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”. However this investigation was never ordered by the Ministry.

173. 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: “This is yet another instance where the Ministry has failed to act on a proven case of gross illegality. Instead after whiling away more than six months, it has still chosen to take recourse to its favourite ploy of referring the matter for examination and review to NDAC. As far as culpability part is concerned that has also been staggered indefinitely as the Ministry has till now only conveyed that DCG (I) will constitute an inquiry committee to investigate into the issue. The Committee takes serious umbrage over these more than apparent dilatory tactics being adopted by the Ministry to somehow delay action against the wrongdoers. The Committee, therefore,

reiterates its Recommendation that responsibility be fixed in this case without any further loss of time and the approvals granted be reviewed in the light of latest scientific evidence regulatory states in developed countries, particularly in Belgium, the country of its origin, equally quickly.”

174. We 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 on September 17, 2015 informing us that “no separate orders in this regard have been issued by the MOHFW” meaning therefore that no investigation was ordered despite a written commitment being made to this effect to Parliament. As of March, 2016 media reports indicated that the drug was still available in the market.²³

175. Improper 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

²³ Zeba Siddiqui, *Pharma crusader Dinesh Thakur takes India’s drug regulators to court*, Reuters Mar. 7, 2016

available at <http://in.reuters.com/article/india-pharma-whistleblower-idINKCN0W90C8>

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.²⁴ The entire observations of the Hon'ble Committee are reproduced as follows: "Letrozole discovered by Novartis, is an anti-cancer drug for use only in postmenopausal women and is contraindicated (not permitted) to be used in women of reproductive age. If it is to be used for any other indication except breast cancer, then the drug is categorized as a New Drug under Indian laws. On 10-04-2007, DCGI approved the use of letrozole for improving female fertility. The Drugs and Cosmetic Rules require that while approving a drug for use in females of reproductive age, animal studies are to be done in this specific group. No such

studies were done in India. The innovator also did not conduct such studies abroad because there was no plan to use letrozole in women of reproductive age. Under Indian rules, Phase II studies should have been conducted before Phase III since such studies were not conducted anywhere. Permission to conduct Phase III studies was given without prior Phase II studies. Phase III clinical trial was conducted on just 55 women by three doctors in private practice while the minimum requirement as per mandatory Good Clinical Practice (GCP) rules is at least 100. After approval, the sponsor, Sun Pharmaceuticals did not submit periodic PSURs due every six months as required by law. No action was taken against the Company in such a sensitive case since India is the only country where the drug is permitted to be used for female infertility. Post-marketing data is crucial and critical in detecting adverse effects both in women and babies born to them if they use letrozole before the onset of pregnancy. Clearly there was a serious

²⁴ Kounteya Sinha, *Finally, expert panel bans fertility drug Letrozole*, TIMES OF INDIA, October 18, 2011 available at <http://timesofindia.indiatimes.com/india/Finally-expert->

panel-bans-fertility-drug-Letrozole/articleshow/10395119.cms

lapse on the part of CDSCO. In the wake of media outcry, in a diversionary move, the DCGI instead of investigating the allegations of regulatory lapse and taking corrective measures referred the matter to clinical experts, DTAB etc. on the restricted issue of safety and efficacy. DCGI is expected to take action against those CDSCO functionaries who colluded with private interests and got the drug approved in violation of laws. The drug has since been banned by the Ministry for use in female infertility."

176. 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. The Committee, therefore, reiterates their Recommendation with all force at their command and desire immediate and exemplary action against officials of CDSCO who colluded with private interest and got the drug approved in violation of laws at once and without the delaying instrument of another inquiry Committee."

177. We 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 on September 17, 2015 informing us that "no separate orders in this regard have been issued by the MOHFW".

178. Improper 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 committed 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 allegedly banned in its country of origin (Denmark) which means that it cannot be imported into India. 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. The Committee's observations are noted below:

"7.45 The Committee is of the opinion that there must be some very good reasons for Danish Medicine Agency (Denmark) not to approve a domestically developed drug where an anti-depressant drug would perhaps be in greater demand as

compared to India. Curiously, Deanxit is allowed to be produced and exported but not allowed to be used in Denmark.

7.46 The Committee feels that the DCGI should have gone into the reasons for not marketing the drug in major developed countries such as United States, Britain, Ireland, Canada, Japan, Australia just to mention a few. United States alone accounts for half of the global drug market. It is strange that the manufacturer is concentrating on tiny markets in unregulated or poorly regulated developing countries like Aruba, Bangladesh, Cyprus, Jordan, Kenya, Myanmar, Pakistan, and Trinidad instead of countries with far more patients and profits. Many of these developing countries are handicapped due to lack of competent drug regulatory authorities. Instead of examining and reversing regulatory lapses, DCGI has referred the matter to an Expert Committee to look at the isolated and restricted issue of "safety and

efficacy" instead of unlawful approval in the first place.

7.47 The approval of this drug is in clear violation of the Drugs and Cosmetics Rules. As per Rules, a New Drug is deemed to be a New Drug for four years. After four years, the State Drug Authorities have the powers to issue manufacturing licenses without reference to DCGI. Therefore, if initial approval is given unlawfully by the DCGI, the doors open for other manufacturers to market the drug after four years. This is exactly the situation with FDC of flupenthixole and melitracen. The Committee recommends that in view of the unlawful approval granted to Deanxit, the matter should be re-visited and re-examined keeping in mind the regulatory status in well developed countries like Denmark, the country of origin; the United States, Britain, Canada, European Union and Japan etc. It is important to keep in mind that in Europe, there are two types of marketing approvals:

Communitywide (cleared by European Medicine Agency) and individual regulators of member nations. EMEA is known to clear drugs after great deal of scrutiny while the competence and expertise of drug regulatory authorities of individual nations is not uniform and varies greatly from country to country."

179. 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. Relevant observations by the Hon'ble Committee are reproduced below:

"3.100 The case of Deanxit conveys a strong whiff of collusion and cover up, briefly put, in its initial ATN, the Ministry informed the Committee that the matter

had been referred to the 3-member expert committee and hence action would be taken when the recommendation is received. Surprisingly in its final ATN, there is no mention of any recommendation from the 3-member expert committee. In order to investigate the matter, the Committee went into the records of the 3-member expert committee and found a major intriguing omission. In its report to the Ministry, the 3-member expert committee had grouped various cases of wrong doing under heading (a) on pages 4, 13 and 49. However either by design or default, the case of Deanxit (FDC of flupenthixol and melitracen) identified by the Committee as a blatant example of unlawful approval was omitted under the group while other cases were listed. The Committee finds it more intriguing that such an omission was not noticed by the Ministry.

3.105 Deanxit is not allowed for marketing in any of the other advanced countries such as

United States, Britain, EU Community, Canada, Australia and Japan where depression is more common than India. In the United States the two ingredients, Flupenthixol and Melitracen are not even individually allowed to be marketed.

3.106 In the ATNs, the Ministry has gone out of the way to inform the Committee that the drug "is also marketed in other countries," as if it is a good defence for permitting the use of the drug in India. The Ministry is advised to read Para 7.44 carefully of the Committee's Report where in the Committee has acknowledge that Deanxit is indeed marketed in countries like Aruba, Cyprus, Jordan, Kenya, Pakistan, Trinidad etc and some other developing countries which are handicapped by lack of competent drug regulatory system.

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.

3.112 The Committee, therefore, reiterate that concrete and exemplary action by the Ministry on (a) unlawful approval against functionaries of CDSCO (b) reversal of unlawful approval, (c) unlawful promotion by Lundbeck.

3.113 In the opinion of the Committee it is an open and shut case that needs immediate action, not promise of prolonged fruitless deliberation designed to delay action. Why should the people of India consume a questionable drug approved in a questionable manner even for a day longer, more so when the drug regulator of the innovator country Denmark is not allowing its use within its jurisdiction but allowing its export to developing

countries with weak or non-existent drug regulation?"

180. We 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 in the Final ATR. Nevertheless in the response, the MOHFW did state that it had apprised the Standing Committee that an investigation would be ordered into the approval of Deanxit and that no separate order for an investigation in this regard had been issued by the MOHFW.

181. As an aside it is also necessary to point out that when the well-known Dr. Chander M. Gulati who is the editor and owner of the Monthly Index of Medical Specialities published the fact that the drug Deanxit was banned in Denmark and other countries, the manufacturer Lundbeck, through its Indian subsidiary filed a criminal defamation complaint against Dr. Gulati before the court of the Chief

Metropolitan Magistrate in Bangalore. Initially the court dismissed the complaint and the revisional court

upheld the decision but eventually the High Court set aside these orders and ordered the trial court to take cognizance of the complaint and initiate a criminal trial.²⁵ The current status of the case is not known. It is also pertinent to mention that after the Central Government used its powers under S. 26A of the Drugs & Cosmetics Act to ban Deanxit through a notification on 18.06.2013, the Indian company selling the drug in India challenged the notification before the Karnataka High Court. In a judgment dated August 14, 2013 the Karnataka High Court set aside the notification banning Deanxit due to procedure not being followed.²⁶ The Government was ordered to once again assess the information provided by the manufacturer and decide on the approval of the drug. In 2014, the media reported that this drug was once

again banned by the government.²⁷ The current status of the drug is not known.

182. Approval of placenta for new indications: As with the cases above, the Standing Committee had noted in its 59th Report that a company's request for approving its drug 'placenta' for additional indications had been granted in a clear violation of the rules. The Hon'ble Committee also noted that the CDSCO had 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 it had informed the Hon'ble Committee that the matter was referred to the Expert

²⁵ *Lundbeck India Pvt. Ltd. v. Dr. Chandra Gulati & Others*. Cri. Pet. No. 4683 of 2011 before the High Court of Karnataka dated July 26, 2012 available at <https://indiankanoon.org/doc/183428285/>

²⁶ *Lundbeck India Pvt. Ltd. v. Union of India* W.P. No. 28354 of 2013 before the High Court of Karnataka dated

August 14, 2013 available at

<https://indiankanoon.org/doc/166489410/>

²⁷ Soma Das, *Lundbeck to seek legal recourse after health ministry bans Deanxit again*, ECONOMIC TIMES, July 25, 2014 http://articles.economictimes.indiatimes.com/2014-07-25/news/52026547_1_lundbeck-deanxit-franxit

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 for not yet ordering the investigation. In pertinent part, the Committee stated: "3.126 The Committee finds the instant response of the Government clear stonewalling to protect the guilty. The matter of inquiring into and taking action against CDSCO functionary who violated the rules to favour the manufacturer by treating a new drug (Placenta extract) as old drug and permitting the use for additional indications, with potential risk to patients, is a very simple open and shut case. In any case the 3-member expert committee instead of straightaway suggesting concrete action has recommended an enquiry, which the Ministry to its great comfort and convenience has interpreted to mean forming an "inquiry committee". Such repetitive references from the Ministry to the 3-member Expert Committee to another "inquiry committee" would mean further delay in taking action, if not placing the issue

in cold storage. In the opinion of the Committee, this is one case where no extraordinary investigative skills or legal acumen is required to fix responsibility and punish the guilty official(s). A rule has been violated, all evidence is on board and the extraordinary interest of the perpetrator(s) is also clearly visible."

183. Notwithstanding these strong comments by the Hon'ble Standing Committee the MOHFW is yet to take any action against the CDSCO. We 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.
184. Improper 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:

“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.

7.52 The Committee expresses its deep concern, extreme displeasure and disappointment at the state of affairs as outlined above. The Ministry should ensure that the staff at CDSCO does not indulge in irregularities in approval process of new drugs that can potentially have adverse effect on the lives of people. It is difficult to believe that these irregularities on the part of CDSCO were merely due to oversight or unintentional. Hence all the cases listed above and cases similar to these should be investigated and responsibility fixed and action taken against

erring officials whether currently in service or retired.”

185. 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. We 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”.

Section B: Missing files at the CDSCO

186. 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).The exact observations of the Committee are reproduced as follows:

“7.12 Out of 42 drugs picked up randomly for scrutiny, the Ministry could not provide any documents on three drugs (pefloxacin, lomefloxacin and sparfloxacin) on the grounds that files were non-traceable. All these drugs had been approved on different dates and different years creating doubt if disappearance was accidental. Strangely, all these cases also happened to be controversial drugs; one was never marketed in US, Canada, Britain, Australia and other countries with well-developed regulatory systems while the other two were discontinued later on. In India, all the three drugs are currently being sold.”

187. Since the files were missing, the Committee was unable to examine the conditions of approval. It merely ordered the government to reconstruct the files.

188. “Missing files” in a government department are 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. Under the [Public Records Act, 1993](#) each government office is required to maintain records in a prescribed format. Section 7 of this legislation requires the Records Officers in every department of government to take “appropriate action” in case files go missing. The Central Information Commission (CIC) which hears complaints and appeals under the Right to Information Act, 2005 had ruled in the case of [Om Prakash v. Land & Building Dep. GNCTD, Delhi \(CIC/DS/A/2013/001788SA\)](#) that all cases of missing files had to be thoroughly investigated and responsibility for the missing files had to be fixed on a public servant. The CIC’s judgment also cites a Delhi High Court judgment where the court held that even if the information was found through other means, responsibility had to be fixed for the missing files. If criminality, such as theft or corruption in suspected the missing files case, a FIR is

required to be filed with the local police station that has the jurisdiction over the office.

189. In the case of these three missing files, the government never filed a FIR or conducted a criminal investigation to fix responsibility for the missing files. We filed a RTI application with the Ministry of Health to determine the status of the files and more specifically on the point of whether an investigation had been conducted into the cause that made these files go missing. The Ministry answered a couple of questions on the status of the files but transferred the main question of whether the investigation had been conducted to the CDSCO. The one line reply from the CDSCO, on September 29, 2015, was as follows: "No such formal complaint was conducted; however, continuous efforts were made by CDSCO to trace out these files at various locations where the old files were stored".

Section C: The unimplemented recommendations of the Katoch Committee Report

190. 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. As a part of the exercise, the committee asked the CDSCO to present a self-assessment of its functioning. Some of the disclosures made by the CDSCO in this report are revealing of the rot within the organisation. Sample this excerpt from the report on page 33:

"From early days the CDSCO has been without medical specialists. Therefore, CDSCO was engaging consultation of outside experts for evaluation of safety & efficacy of drugs.....the present cumbersome system of providing TA/DA to the

outside experts is a major constraint in getting external expertise. It further requires a well-supported secretarial assistance."

"Resource in terms of manpower and other infrastructural facilities like working area, archiving, maintaining software based data bank etc. are grossly inadequate for effective functioning in various multi-disciplinary activities of CDSCO."

"There is a weak administrative infrastructure with respect to handling of administrative activities like service matters, budgets, recruitment, procurement matters etc."

191. The remaining "confessions" in the self-assessment report pertain to the lack of training for key personnel, inadequate access to the latest medical literature, inadequate working space, inadequate archiving facilities and non-existence of a data bank of all drug licences issued by various authorities in the country. While some of these issues can be solved by throwing more money at the problem, as the government has announced recently under the 12th Five year plan, there is a

need for radical structural changes in order to make this organization accountable to the people of India. The Katoch committee had recommended a detailed study of 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 Mashelkar 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.”

192. We filed a RTI application with the MOHFW 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. The Ministry has therefore ignored the recommendations of its own experts. It is imperative to conduct such a study of the CDSCO because as explained

earlier there are serious structural defects in the CDSCO which cannot be cured by merely adding more personnel or funds.

Section D: The qualification criteria for the post of the Drug Controller General of India (DCGI)

193. One of the issues raised in the 59th Report of the Parliamentary Standing Committee on Health & Family Welfare was that of appropriate qualifications for the post of the Drug Controller General of India (DCGI), who heads the CDSCO. The main concern expressed by the committee was that unlike regulators in the US and UK both of which are usually headed by persons qualified as medical doctors, the Indian regulator has usually been headed by a pharmacist. This is because of the manner in which the law prescribes the qualification criteria for the post of the DCGI. As per Rules 49A and 50A of the Drugs & Cosmetics Rules, 1945 a licensing authority or controlling authority is required to be either (a) a graduate in pharmacy or pharmaceutical chemistry (B.Pharm) or (b) a graduate in medicine with specialization (post-graduation) in clinical pharmacology or microbiology

(MD) and mandatorily have five years' experience in the manufacture of or testing of drugs or enforcement of the provisions of the Act.

194. By necessarily requiring a candidate to have 5 years of experience in manufacturing or testing of drugs, these rules virtually disqualify all medical doctors in India from the post because doctors will rarely have such experience. As a result pharmacists are usually appointed to the position of the DCGI. It is however crucial to have medical doctors or public health professionals heading a drug regulator because the primary responsibility of the DCGI is to safeguard public health – this includes decisions related to drug approvals and clinical trials, both of which are beyond the capability of pharmacists. This is not to say pharmacists have no role – they are a key component of regulating manufacturing but this is only one component of the overall drug regulation.

195. The Standing Committee appears to appreciate this distinction. It comments:

“The Committee fails to understand as to how a graduate in pharmacy or pharmaceutical chemistry (B.Pharm) is being equated with a medical graduate with MD in Pharmacology or Microbiology. Apart from the obvious anomaly, with rapid progress in pharmaceutical and biopharmaceutical fields, there is urgent need to revise the qualifications and experience as minimum eligibility criteria for appointment as DCGI. The Committee is of the view that it is not very rational to give powers to a graduate in pharmacy, who does not have any clinical or research experience to decide the kinds of drugs that can be prescribed by super specialists in clinical medicine such as those holding DM and PhD qualifications and vast experience in the practice of medicine and even research.”

196. Furthermore, the committee also stated the following:

“On a larger plane, the Committee is disillusioned with the qualifications provided in the age old Rules for the head of a crucial authority like CDSCO. The extant Indian system is nowhere in so far as sheer competence and professional qualifications are concerned when compared with countries like USA and UK. There is, therefore, an urgent need to review the qualifications, procedure of selection and appointment, tenure, emoluments, allowances and powers, both administrative and financial of the DCGI.”

197. As a result of the Standing Committee's recommendations, the Government of India constituted an Expert Committee to suggest the qualification criteria for senior level posts in the CDSCO including the DCGI. The Committee initially comprised of three persons: Mr. Satyananda Mishra, Former Secretary of the DoPT, Dr. M.K. Bhan Former

Secretary Dept. of Biotechnology and Dr. Ranjit Roy Choudhury Prof. Emeritus Pharmacology. Later, the Committee co-opted two more persons, both of whom were former DCGIs: Dr. Prem Gupta and Dr. Ashwini Kumar. The decision to include the former DCGIs was a direct conflict of interest because such a review exercise requires an objective mind – former DCGIs are not going to admit that the existing criteria in the law under which they were appointed was flawed and that they were unfit for the job they held. It should therefore not surprise anyone that the final report of the committee hardly makes any radical recommendations. In fact, the final report is only 9 pages and is very poorly researched and reasoned.²⁸ The only small mercy is that the report drafted recommendations to change the mandatory requirement of experience in testing or manufacturing of drugs and instead, allow for clinical research or other related research areas to be considered in senior level appointments to India's drug regulator. This may make it easier to appoint medical doctors to

²⁸ Report of the Expert Committee set up to suggest recruitment rules/job description for senior level posts

in Central Drugs Standard Control Organization; June 1, 2015.

the post of DCGI. This final set of recommendations does not however delete the criteria which allows pharmacists to be appointed – it merely upgrades the criteria from a mere Bachelor's degree to a Master's Degree. Even these recommendations are yet to be implemented by the government.

198. Changing the qualification criteria for this critical public health role isn't going to be an easy task. The rank and file of the CDSCO consists of officers who are primarily pharmacists or hold similar degrees – changing qualifications at the top is seen to impede their chances of climbing the organisational ladder. At the same time, the appointment of a person from outside the fraternity opens the door to even more accountability which could disadvantage vested interests.

199. A NGO by the name of Delhi Pharmaceutical Trust (DPT) has already demanded that the Ministry not change the qualification criteria. The

Trust's managing trustee told Pharmabiz:

“Top regulatory head positions like the DCGI involve effective implementation and overseeing drugs and pharmaceuticals import, approval of new drugs, manufacture, sale and distribution, Expert knowledge of pharmacy and pharmaceuticals along with administrative experience in these areas is vital to provide positive leadership and effective enforcement of drugs. In the current global regulatory scenario, maintenance and growth of Indian pharmaceutical sector is key to the country”.²⁹

200. Similarly, an industry lobby group called the Indian Pharmaceutical Association (IPA) has urged the government to not change the qualification criteria. In a letter dated November 5, 2014 the Association wrote to the Health Minister stating:

“The Drug Controller General of India is a torch-bearer to the

²⁹ Nandita Vijay, *DPT urges Ministry of Health not to make changes in Recruitment Rules for DCGI post, other top jobs in CDSCO*, PharmaBiz – Jan. 19, 2015 available at

<http://www.pharmabiz.com/NewsDetails.aspx?aid=86219&sid=1>

pharmaceutical industry. Considering the enormous responsibilities that this person has to shoulder, the DCGI should have the technical expertise in the pharmaceutical field rather than mere knowledge about clinical applications of pharmaceuticals to do justice to the post. We strongly believe that a Post Graduate & Ph.D. degree holder in Pharmacy with adequate experience is best suited for leading the CDSCO and request you to make provisions so that none other than a post graduate & Ph.D. holder in Pharmacy can lead CDSCO as Drugs Controller General of India".³⁰

201. Such arguments represent a myopic view of drug regulation for reasons already discussed above i.e. they fail to understand that drug regulation is much more than merely supervising manufacturing processes of the industry.

202. Apart from the issue of qualifications of the DCGI, there is also the issue of states like Andhra Pradesh and Telangana of appointing officers from generalist services like the Indian Police Service (IPS) and the Indian Administrative Service (IAS). This is contrary to other states where the drug controller usually climbs up the ranks of the drug control department. In fact, IAS and IPS officers rarely head specialist bodies requiring specialised scientific skills. In fact, the All India Drug Control Officer's Confederation has been protesting against this practice for several years now.³¹

Section E: The missing NSQ database

203. 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 which lists 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

³⁰ Letter from Indian Pharmaceutical Association to the Health Minister dated November 5, 2014, available at: <http://www.ipapharma.org/news/Recruitment%20Letter%20-%20202.pdf>

³¹ <http://www.deccanchronicle.com/140707/nation-current-affairs/article/no-ias-or-ips-officer-head-drug-control-administration>

various drug manufacturers. In its 59th Report, the Hon'ble Standing Committee had pulled up the MOHFW on the lack of accurate databanks whereby states shared information with each other on information technology platforms. 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 on their own websites, 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 XLN database. 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.

204. Although several drug controllers aren't making information easily available online, this is not to say that they don't have records maintaining such information on NSQ drugs and prosecutions. 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. None of these registers are however made proactively available on the websites of the drug controllers.

205. As per Section 4(a) of the Right to Information Act, 2005 all this information is required to be made available proactively on the internet. In pertinent part, the provision states "Every public authority shall maintain all its records duly catalogued and indexed in a manner and the form which facilitates the right to information under this Act and ensure that all records that are appropriate to be computerised are, within a reasonable time and subject to availability of resources, computerised and connected through a network all over the country on different systems so that access to such records is facilitated." Unfortunately most states don't make such information proactively available. We had to file RTI applications to procure this information. While Maharashtra, Tamil Nadu, Andhra Pradesh and Karnataka were helpful in sharing information under the RTI Act when we made requests, some of the states like Uttarakhand and Himachal Pradesh, were less than cooperative. Although some information was provided, it did not appear to be as accurate as some of the other states.

206. Since none of these authorities are following the mandate laid down in the RTI Act, the Central Government should seriously consider the possibility of notifying specific rules under the Drugs & Cosmetics Act requiring all states to contribute information to a central database maintained by the CDSCO. The database should be easily searchable by procurement officers, medical doctors and the general doctor. For example, before a procurement officer places an order for a particular batch of medicines, he should be able to check the track record of the manufacturer on the database which should ideally contain information, from all states, on the number of times the manufacturer's drug samples have failed quality tests in govt. labs, the number of times a licence was suspended or cancelled for any product, whether there was a prosecution and the result of the prosecution. Increase transparency will automatically result in manufacturers with a poor track record being sidelined by market forces and that in itself, can be a powerful tool for increasing the quality of drugs in the market.

Part V – Sub-standard drugs in the public procurement system

207. Over the last decade, there have been a number of audit reports by the Comptroller & Auditor General (CAG) pointing to a major problem of NSQ drugs in publicly funded institutions and schemes run by the Ministry of Health through its network of hospitals such as the Central Government Health Scheme (CGHS), Armed Forces Medical Stores Depot (AGMSD) and the extensive network of hospitals maintained by the Indian Railways. While a likely culprit for the high number of sub-standard medicine is the lowest bidder system followed by public authorities, the main culprit is the overall poor regulation by the CDSCO and Ministry of Health. Due to the lack of faith in the CDSCO's regulatory process, each of these public authorities conduct their own quality testing on each batch that is procured from the market. Not only is the process time consuming, it is expensive. What is perhaps even more surprising is that

several public funded hospitals actually end up issuing the medicines even before they get the results from the quality testing lab because the labs take too long with the testing process. This happens rather frequently according to CAG reports. As a result patients in public funded hospitals frequently end up having NSQ drugs. These various issues can be tackled through stricter and more uniform blacklisting norms. As of now each public authority appears to be following a different set of blacklisting norms and there is very little information sharing even within organisations like the Indian Railways, not to say anything about the non-existent inter-institution sharing. A few of these issues are discussed in more detail below.

Section A: The CAG Reports auditing the CGHS, AFMSD & the Indian Railways

208. The CAG reports on public hospitals under the Ministry of Health: CAG Report No. 20 of 2007 audited various hospital and establishments operating under the Ministry of Health.³² Most of these hospitals provide services to public servants under the Central Government Health Scheme (CGHS). As per the audit report, the entire procurement process was punctuated by completely arbitrary behaviour and lack of set processes or guidelines. One of the key deficiencies pointed out with regard to quality control was the failure of hospitals, including AIIMS to carry out mandatory testing on all procurements before issuing.³³ The CAG report spurred a more detailed examination of the CGHS processes by the Public Accounts Committee (PAC) of the Lok Sabha in its 24th Report (2011) and 84th

Report (2013).³⁴ Some changes were made by the MoHFW, but clearly the changes were not enough because as noted by the PAC in its 22nd Report (2015), sub-standard drugs in the CGHS were still a problem.³⁵ As noted by the Committee in this report, between 2009 and 2012 CGHS, Bombay had reported Rs. 28.45 lakhs worth of drugs as sub-standard.³⁶ Of these medicines, stock worth Rs. 15.66 lakhs had already been issued to patients. The Committee had noted "Such instances highlight the absence of a robust mechanism for quality assurance, which exposes the patients to the hazards of sub-standard medicines and drugs".³⁷

209. The CAG Reports on AFMSD: 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).³⁸ As is the case with the CGHS system and the Indian Railways, the AFMSD is also

³² Report No. 20 of 2007 for the period ended March 2006 – Performance audit of Procurement of medicines and medical equipment, Comptroller & Auditor General of India available at <http://saiindia.gov.in/content/report-no-20-2007-period-ended-march-2006-performance-audit-procurement-medicines-and>

³³ *Ibid* at para 7.1.8

³⁴ Procurement of Medicines and Medical Equipment, Public Accounts Committee (24th Report - 15th Lok Sabha), 2010-11 & Procurement of Medicines and Medical Equipment, Public Accounts Committee – Action Taken by the Government on

the Observations/Recommendations of the Committee contained in their Twenty-Fourth Report (84th Report - 15th Lok Sabha), 2012-13.

³⁵ Procurement of Allopathic Drugs in CGHS, Public Accounts Committee (22nd Report - 16th Lok Sabha), 2015-16.

³⁶ *Ibid* at p.5.

³⁷ *Ibid* at p.5.

³⁸ Report No. 18 of 2012-13, Performance Audit of Medical Establishments in Defence Services, Comptroller & Auditor General of India at p.72-73.

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.**³⁹ 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. The trend therefore has been to reduce local procurement and

conduct more procurement through centralised procurement mechanisms.

210. The CAG Reports on the Indian Railways: In its Report no. 28 of 2014 on the Railways Hospitals, the CAG noted that substandard drugs worth Rs. 21.45 lakh were supplied to 20 hospitals over 8 different zones of the railways.⁴⁰ The actual figure is most likely higher because as also noted in the same CAG report, the railways hospitals were not conducting mandated pre-dispensing testing of consignments i.e., each consignment of these drugs is required to be tested before being issued to patients.

211. Even in cases where pre-dispensing quality testing is conducted, it was found that in 8 hospitals, over 4 railways zones, had dispensed these drugs to patients and then received the test reports indicating that the drugs were NSQ.⁴¹ In one case in Kolkata, 93.8% of a batch of drugs were dispensed before the test reports returned from

³⁹ Report No. 18 of 2012-13, Performance Audit of Medical Establishments in Defence Services, Comptroller & Auditor General of India at p.72-73.

⁴⁰ Report No. 28 of 2014, Performance Audit of Hospital Management in Indian Railways, Comptroller & Auditor General of India at p. 32.

⁴¹ *Id.*

the lab.⁴² In most of these cases, CAG noted that information regarding these suppliers of NSQ drugs was not shared on railnet, "an internal portal", for information to other zones. In conclusion, the CAG noted "Thus, the existing system of ensuring sample testing and replacement of substandard drugs was not adequately effective. Zonal Railways failed in initiating action against the firms supplying substandard drugs and also against the officials responsible for violating the extant instructions in regard to drug analysis. Further, delayed receipt of reports of drug analysis defeated its objective of providing quality drugs to patients."⁴³

212. Independent of the CAG report, we also filed a RTI application with the Ministry of Railways asking for the names of all the pharmaceutical companies blacklisted by the Indian Railways. To our surprise, we learnt that the Indian Railways does not have a single consolidated blacklist of all pharmaceutical companies which have been debarred from supplying to the Railways because of poor quality

products that they supply. Instead our RTI application was transferred to each zonal railways office. We found that each zone had its own blacklist thereby giving rise to the probability that a supplier blacklisted by one zone can still supply to other zone. Of all the zones which provided replies, only the Western Railways, NorthWestern Railways, North-East Frontier Railways & Eastern Zone even had a blacklist. Some of the companies on the list were rather big names like Biocon (blacklisted for Rosuvastatin), RPG Life Sciences (blacklisted for Atorvastatin), Sandoz, Alkem, Alembic Pharmaceuticals, Abbot etc. Some manufacturers like Ind-Swift & CMG Biotech Pvt. Ltd. were blacklisted for all of their products, while the others were blacklisted for only specific drugs that they supplied. Most of the other zones like the Southern Railways, Northern Railways, South Central Railways, East Coast Railways all claimed that they had not blacklisted even a single manufacturer. The lack of a consolidated blacklist is likely creating windows of opportunity for the manufacturers of sub-standard drugs to

⁴² *Id.*

⁴³ *Id.*

supply to one zone even after being blacklisted by others.

Section B: The variance in black listing norms followed by the CGHS, AFMSD & the Indian Railways

213. The CGHS blacklisting guidelines are contained in the “Procurement and Operational Manual for Medical Store Organisation and Government Medical Store Depots”. The guidelines basically borrow the classification of various defects with sub-standard medicine from certain DCC Guidelines which creates a classification mechanism of Category A, Category B & Category C defects. In the context of the procurement manual, Category A defect in a product results in the supplier being barred for 3 years and if there is a repeat, then the supplier is barred from supplying any products. Category B defects are treated similarly. Such a system of blacklisting is however rather superficial and fails to understand the nature of the pharmaceutical industry.
214. If a particular batch of medicine fails quality control testing at a certified GMP manufacturing facility (as all

Indian pharmaceutical facilities are required to be), it would mean that the facility is not GMP compliant because by their very nature, GMPs create a fool proof mechanism to ensure quality. Every batch has to be tested before it is shipped and the manufacturer has to test the samples before shipping out commercial supplies. In many cases in India, manufacturing problems arise due to non-compliance with GMPs and the defects within a particular batch are merely a symptom of a larger problem within the company. This is the reason why we see a string of warning letters from foreign regulators to the Indian pharmaceutical industry. Therefore, when a public authority detects quality issues with a particular batch of drugs, it should conduct a deeper investigation and determine the reasons for the problem – in some cases it could be purely a case of cheating or fraud by the supplier to make more profits. In such a case, the entire manufacturing facility should be banned because there is no point of banning the supplier only for the one product which has failed the quality control test. In other cases, it may be human error, in which case a lesser penalty may be levied on the supplier.

215. MoD's Policy Regarding Quality Assurance of Drugs and Punitive Action:

This policy laid down by the Directorate of Quality Assurance (Stores) follows the same logic as the CGHS guidelines although the parameters for classifying defects are entirely different.

216. The Railways' blacklisting policy: The Indian Railways has its own Drug Procurement Policy, 2014. Unlike the MoD or the CGHS guidelines, the Railways does not lay down a product specific blacklisting policy. The guidelines states that if there are adverse reports regarding the performance of a firm, the railways officers will inspect the facility and if the firm continues to fail to comply with orders of the Railway to improve quality it will be deregistered. It is not clear how railways officers are going to determine whether a pharmaceutical plant is GMP compliant. Further, from the blacklists provided to us by different zones of the Railways, it is quite clear that some zones like the Western Railways are merely following product wise bans.

C. The need for a public procurement law to specifically regulate procurement of medicine

217. As can be seen from above, the public procurement of drugs in just these three agencies is badly in need for reform. Apart from these agencies, there are also major public funded programs like *Jan Aushadhi* which procure their own share of drugs for distribution to the general public. Given the sheer volume of public funds that are being spent on the procurement of medicine, it is fair to conclude that even a small percentage of drugs failing will not only have public health consequences for a large number of citizens but will also results in crores of rupees being wasted on drugs which don't work. Given the sheer volume of public funds being spent on the procurement process, it would be advisable for the government to leverage this purchasing power to force the industry to improve standards. It can achieve this goal by enacting a common public procurement law for the purchase of medicine by any public funded institution.

218. The law should prescribe a common blacklisting criteria, whereby once a company is blacklisted by one entity, the company cannot bid for any other tenders from any other public funded institution procuring medicine. The second important function of such a law should be to force all public procurement institutions to share information on sub-standard suppliers and blacklists. As explained earlier, such a law is required because even within organisations like the railways there is little sharing of information between different zones on blacklisted suppliers.