

An Analysis of Adequacy of Indian Drugs Regulatory Provisions in Combating the Problem of Spurious and Adulterated Drugs

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ABSTRACT

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In 2003, Mashelkar committee found that 10% of available drugs in India are Sub-standard. Recently (June 2011) Honorable Apex Court of India observed that the Drugs Act of India does not has deterrence. It has to be analyzed that whether mere enhancing the punishment under the Act shall make it deterrent. It has to be find out what other changes in the Act is required to make it more effective. Drugs Control Authorities need power of interrogation and power to ask a person to make statement. These powers shall help them to gather evidence against the culprit and these powers shall enable them to conclude the investigation to a logical end.

The provisions in Drugs and Cosmetics Act, 1940 and Rules, 1945, are main tools to regulate manufacture, sale and distribution of Drugs and Drugs-devices in India. These have been supported by Pharmacy Act, 1948, Psychotropic and Narcotic Substances Act, 1985, The Drugs Magic Remedies (Objectionable Advertisements) Act 1954, and Rules 1955, etc. The Ministry of Health and Family Welfare of Government of India constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar, Director General of CSIR to undertake “ A comprehensive examination of drug regulatory issues, including the problem of spurious drugs” on January 27, 2003. On June 8, 2011 Honorable **Supreme Court of India** observed and remarked something regarding adequacy of Drugs Regulatory Provisions of India¹. It is an indication of a grave situation. They observed, **“In this country, if there are two laws that need to be changed or amended to act as a deterrent, they are laws relating to anti-corruption and sale of spurious drugs”**. They further observed: **“...Similarly, take the case of sale and supply of spurious drugs which is rampant in the country. You may prosecute a person but he would get away paying a fine of Rs 500. But by that time, the patient would be dead. So you need to amend these laws”**.

Three decades ago (1982), Honorable Justice Mr. Ajit Singh Bains of **Punjab and Haryana High Court** expressed their

deep concern on availability of spurious/ adulterated drugs in market and held that:

“It is really regrettable that after 35 years of attaining freedom, the adulteration of medicines and articles of food has reached the saturation”².

Mashelkar Committee has submitted its report in November 2003. This was the first endeavor to assess the achievement of “The Drugs and Cosmetics Act, 1940” since its enforcement. Paragraph 8.4.2. of the report states:

“Based on the samples tested by the State Authorities, data were analyzed for the period 1995-2003. According to these data, the extent of sub-standard drugs varied from 8.19 to 10.64% and of spurious drugs varied between 0.24 % to 0.47%”.point. **It is most heinous crime and the state in my view, must think over the matter for taking stringent steps to eradicate this menace....”³**

The crime under Drugs and Cosmetics Act, 1940 and Rules 1945 may be categorised as Socio-economic crime. The Criminal Jurisprudence states:

“when the advantage to be gained from the wrongful act is great and the risk of detection is small the human nature is very likely to be tempted to commit such wrong”.

The illustrations as shown in the table 1 and their analysis shall justify the above mentioned proposition of Criminal Jurisprudence.

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Table1: Outcome of Legal Cases against the Unscrupulous Manufacturer and Seller of Drugs

1.	S.C. ⁴ Cr. App. 116/1969	D.N.S. inj. containing toxic amount of lead nitrate which resulted death of 13 persons on administration in a hospital.	None were found guilty of the offence even than it was proved that adulterated drug was manufactured by the Company.
2.	H.C. Allahabad ⁵ Cr. App.673/1972	Spurious Durabolin injection stocked for sale.	No conviction. "The applicant is fully protected by clause 19(3) of the Act".
3.	H.C. Madras ⁶ Cr. App. 482/1977	Manufacture of sub standard drug.	The defect in the Act has to be rectified; however it is the business of legislature. Accused declared acquittal.
4.	H.C. Punjab and Harayana ⁷ Cr. Rev. 755/1979	Public analyst declared the sample not of standard quality as it did not contain trace of drug (Dexamethasone).	No conviction.
5.	H.C. Madhya Pradesh ⁸ Cr. Misc. 2000/1987	I.V. fluid sodium chloride injection found to contain particles of foreign matter.	No conviction. Offence could not be established as the particles found were not analyzed.
6.	H.C.Patna ⁹ Cr. Misc. 10291/1993	Manufacturing Operations were found being conducted by unskilled labours. Drug found not of standard quality.	No conviction. Director of the firm is not responsible for the act.
7.	H.C. Madras ¹⁰ Cr. App. 396/1998	Collection and transfusion of whole human blood without any test and without blood bank licence.	No conviction.
8.	H.C. Punjab and Harayana ¹¹ Cr. Misc. 30908/1998	Drug found not of standard quality. Prosecution filed after expiry date.	Court observed no ground for complain as manufacturer was not given chance for re-testing in CDL.
9.	S.C. ¹² Cr. App. 529/1998	Sodium Chloride injection found not of standard quality.	Director cannot be prosecuted.
10.	S.C. ¹³ Cr. App. 300/2001	Manufacture of sub standard drug.	To adopt the course of acquitting such offending manufacturers only on the legislative lacuna would be hazardous to public health.
11.	H.C. Karnataka ¹⁴ Cr Rev. 40227/2003	Drug declared not of standard quality by Government analyst.	No action can be taken against the manufacturer on government analyst test report.
12.	H.C. Calcutta ¹⁵ Cr. Rev. No. 2863/2004	Dead frog found inside bottle of "Bexiton" syrup.	No conviction.

*S.C. -Supreme Court of India, *H.C. – High Court, *Cr. - Criminal, *App. –Appeal, *Rev. – Revision, *Misc. -Miscellaneous

Case enlisted at s. no.1 is a judgment delivered by the Honorable Supreme Court of India in 1972⁴. Administration of Glucose in Normal Saline Solution Injection manufactured by Sanitax Chemical Industries Ltd, Baroda, caused death of 13 patients in a hospital. On analysis of the drug, it was found that the drug contained lead nitrate much more than permitted limit and it was in toxic range. Thus the inference was that toxicity of lead caused the death. The investigation revealed that in the store of the manufacturing unit there was no sufficient stock of Sodium Chloride to charge the particular batch and in the store, packets of Sodium Chloride and Lead Nitrate were found stored in the same drum. Test for Lead

Nitrate in the raw materials or finished product were not performed although it was prescribed. Prosecution filed against six accused under section 18(1)(a), 18 (a)(v), 27 and Section 304 A of Indian Penal Code. The accused were Managing Director, Directors, Manufacturing Chemist, Chief Analyst, Works Superintendent of the firm. All of the accused were discharged for the alleged offence under the Drugs and Cosmetics Act, 1940 by the various Honorable Courts in the battle of law. Managing Director and Directors were discharged as there was no proof that they were in charge of the manufacturing unit on the day the drug was manufactured. As per the provision of section 34 of the Drugs and Cosmetics

Act, 1940, it is required that to fetch punishment the prosecution has to prove that the accused master of the firm was in charge of the day to day business of the firm on the day offence committed. Other three accused were discharged on the ground of the interpretation of the section 18 of the Drugs and Cosmetics Act, 1940 by various Honorable Courts. Various Honorable High Courts and Honorable Supreme Court of India interpreted section 18 as:

“ only master and not servant/s have penal liability for the violation of section 18 of Drugs and Cosmetics Act”.¹⁶

However, Chief Analyst and Manufacturing Chemist awarded punishment under section 304-A of Indian Penal Code (304A. *Causing death by negligence*) by trial court. Both of the accused filed appeal in Additional Sub- Judge Court. The Additional Sub-judge discharged both the accused. An appeal was preferred by state in the Honorable High Court against this order of Additional Sub-Judge. The Honorable High Court Convicted the Manufacturing Chemist and discharged Analytical Chemist. The Manufacturing Chemist filed appeal against this order in the Honorable Supreme Court under section 134 (1)(c) of the Constitution of India. The Honorable Court set aside the conviction of the Manufacturing Chemist. Honorable JJ Mr.J.M. Shelat and Mr.P. Jagmohan Reddy of Suprem Court of India observed.

“... In as much as in all cases under Section 304-A there is a casual chain which consists of many links, it is only that which contributes to the cause of all causes, namely, the causa causans and not causa sin qua non which fixes the culpability. In other words, it is submitted that it is not enough for the prosecution to show that the appellant's action was one of the causes of death. It must prove that it is the direct consequence, which in this case has not been established”.¹⁷

On thorough analysis of above case history it is evident that the prosecution case was very clear. The Drugs Regulating Authority meticulously investigated the case and fought the legal battle to last judicial institution. But they failed to get the offenders convicted. This failur puts big question mark on the reliability of provisions of Drugs Regulatory Act and Rules of India.

The case enlisted at s.no.2 is a judgment delivered by the Honorable J.Mr B.D.Gupta of Allahabad High Court. Durabolin injection found stored in a retail shop declared spurious on analysis by Government Analyst. The trail court convicted the proprietor of the shop. The Honorable High court set aside the conviction on the ground that retail has given immunity under section 19(3) of the Act.

The case enlisted at serial number 3 of the above chart is a

judgment delivered by the Honorable J. M.N.Murty of Madras High Court. The Honorable Judge observed: “There were many accused and obviously portion of sample could not be supplied to all accused and the accused declared acquittal by the honorable court on the ground that to get analyzed the portion of sample is a valuable right to the accused and that cannot be denied.” Honorable court further observed:

“The defect in the Act has to be rectified. However it is the business of the legislature and not mines”. And the Height Court has chosen to quite the appellant manufacturer.

Case enlisted at Serial No. 4 of the chart is a judgment delivered by Honorable Judge Mr. Sukhdev Singh Kang of Punjab and Haryana High Court.⁷ In brief the case history states: Drugs Inspector draw sample from a retail shop: Public Analyst declared the sample to be of non-standard quality, misbranded, and adulterated, as it did not contain even a trace of the active ingredient i.e. Dexamethasone; Prosecution filed against the retailer under Drugs and Cosmetics Act, 1940, Sections 18(a)(i)(a)(ii), 19 and 27. The trail court convicted the accused. The accused prefer appeal in Honorable High Court. The accused declared acquittal. The Honorable Court observed:

“...In view of the above discussion, the petitioner has satisfied the requirements of Section 19 (3) of the Act and he cannot be convicted for the offence. In view of this situation the trial of the petitioner shall be an exercise of powers in futility. This shall be, in a way, an abuse of process of law. Taking all these facts into consideration, I allow this revision petition and quash the order dated 17th May, 1979, passed by the Additional Chief Judicial Magistrate Faridkot”.⁷

Case enlisted at Serial No. 5 of the chart is a judgment delivered by Honorable Judge S.L.Srivastava of Madhya Pradesh High Court.⁸ Honorable Judge observed:

“Intravenous fluid Sodium chloride injection found to contain particles of foreign matter. In the absence of analysis of the particles found in the medicine it cannot be held that they were of extraneous substance and not particulate matter of the contents of the medicine coming into existence during storage, subsequent to its manufacture”.

Here it is interesting to note that there is no provision in India to analyze foreign material in parental formulations.

Case enlisted at Serial No.6 of the chart is a judgment delivered by Honorable Patna High Court. The brief case history is as following: A raid party constituted by State Drugs Controller of Bihar found that drug manufacturing work was being supervised and conducted by unskilled labors. No

manufacturing records were available. Sample of drug was drawn and analyzed. It was declared sub-standard by Government Analyst. The Judgment says:

“... for issuing the process against the accused persons, it has to be clearly mentioned that the partners of the firm were in charge of the business of the firm or conducting its affairs when the offence is alleged to have been committed - only the person who was in charge of the business can be proceeded against and, therefore, the prosecution of the petitioners and issue of process for this offence against them bad and cannot be sustained. The complaint petition is also completely silent on the fact whether the partners of the firm, who have been made accused with regard to the said offence, were responsible for conducting the business of the firm. The order of cognizance passed by the learned Additional Chief Judicial Magistrate, Patna City is bad in law and cannot be sustained - there is nothing to show that the provision of Section 34 of the said Act was complied with”.⁹

Again the point to ponder is, whether Drugs Control Authority of India has provided with means to find out the person who is in charge of a manufacturing premises. The Drugs Control Authority of India does not has power to interrogate a person, whom he things to give such information.

Case enlisted at S.No.7 of the chart is a judgment delivered by Honorable Madras High Court.. Drugs Inspector, Madurai visited wholesale premises. There he found a cash memo showing that Dr. Anuradha Ramnath purchased 64 bottles of A.C.D.(Blood Collection Bottles). Dr. Anuradha Ramanath did not have Blood bank licence. Drugs Inspector visited the Nursing Home of Dr. Anuradha Ramnath. The Drugs Inspector found 7 A.C.D. Bottles in her Nursing Home and seized the same. Dr. Ramnath made a statement that she had used 57 Blood Collection Bottles to Collect Whole human blood and all those blood were transfused to her patients. Obviously no test except cross match and group testing were performed for the Blood before these were transfused to the patients. Prosecution filed against her under section 18(c) of the Drugs and Cosmetics Act, 1940. The trail Court acquitted the accused mainly on the ground that there is no evidence to show that the A.C.D. Solutions were stocked for sale and as such, the accused is entitled to acquittal. The Drugs Inspector made appeal in the Honorable Madras High Court against this order. Appeal was rejected and the accused was declared acquittal. The Judgment says:

“-----the prosecution was directed to be launched under Section 18(c) r/w. 27(b)(ii) of the Drugs and Cosmetics Act for having manufactured whole human blood without any

valid drug licence. In the complaint filed by the appellant, it is stated that the accused, Dr. Anuradha Ramnath, purchased 64 bottles of A.C.D. Solution, which is meant only the for licensed blood bank, from Mali Lakshmi Pharma and out of the said 64 bottles, she blended whole human blood and transfused using 57 bottles of A.C.D. Solution, after manufacturing blood The charge framed by the trial Court would reveal that she was accused of having stocked the raw material for manufacturing blood and after manufacture, she sold or distributed the same to her patients for wrongful gain. Merely on the basis of Ex. P-2 confession statement, it cannot be said that the offence alleged against the accused is proved. Therefore, the acquittal is liable to be sustained”.¹⁰

Case enlisted at S.No.8 is a case where prosecution failed due to delay in completing formalities and filing prosecution.

In case s.no.9 the Drug Regulatory Agency failed to book the culprit of manufacturer of Sub-standard Sodium Chloride as because the protection provided by the section 34 of the Act and it is similar to case discussed in s.no.1 and 6.

The case at s.no. 10 shows the frustration of the Judiciary system regarding lacuna in the Act. The agony was expressed by Hon'ble Justices Mr.K.T.Thomas and Mr. R.P.Sethi of Supreme Court of India. The Government analyst declared the drug “Misbranded, Adulterated and spurious”. The Drugs Inspector supplied the copy of government analyst test report to the retailer and the distributor whom name was disclosed under 18A by the retailer. There is no provision in the Act to send copy of test report to the manufacturer and thus no intimation was given to the manufacturer by the drugs Inspector. However prosecution was filed against all the three. The manufacturer succeeded in delaying the proceedings of the trail court for more than decades. The contention of the accused was that there was non-compliance of the provision contained in Section 23(4)(iii) of the Act as the Inspector did not deliver one portion of the sample to the appellant. The Honorable court held:

“when the provision can be interpreted in such a way as to avert absurd consequences it is not congenial to the interest of criminal justice to acquit the manufacturers of forbidden medicines or drugs on technical ground that there is a lacuna in the legislation by not supplying copy of the report of the Government Analyst to the manufacturer in situations. To adopt the course of acquitting such offending manufacturers only on the legislative lacuna (if at all it is lacuna) would be hazardous to public health and the lives of the patients to whom drugs are prescribed by medical practitioners would be in jeopardy.

The case at serial number 11 is an order made by Justice Hon'ble Mr. H.L.Dattu of Karnataka High Court. This order is contrarily to the order made in previous case. The order states as following.

“Provisions of Section 25 of the Act mandates the Drugs Inspector to furnish the copy of the report of the Government Analyst only to a person from whom samples of the drug taken and persons whose name and address is furnished under Section 18-A of the Act. The conclusiveness of the report of the Government Analyst is only against the persons mentioned in sub-section (3) of Section 25 of the Act and that conclusiveness of the facts stated therein cannot be conclusive evidence against the petitioner-Company”.

The case history of s.no.12 is quite interesting and at the same time bitter to swallow. **A dead frog found inside bottle of syrup 'Bexitone'**. The seal of bottle was intact. The purchaser lodged FIR in police station. It was alleged in the FIR that on 6.7.04 the informant purchased one bottle/phial of syrup named 'Bexitone' from Samanta Medical, a medicine shop owned by the petitioner at Mahisadal. After reaching house the informant opened the packet of the said syrup and found inside the bottle/phial a dead frog floating. He showed the bottle containing the floating dead frog to local people, and thereafter, without breaking the seal and opening the bottle he came to the police station and lodged FIR against this petitioner.

The legal battle end without any conviction. The Honorable Court held:

“There was no mensrea at all by this petitioner behind the alleged incident. He was not negligent and his act or omission, if any, did not invite any criminal offence. The petitioner who is a retailer took all possible reasonable care in the instant matter before supplying the medicine bottle to the informant. It would be an abuse of the process of Court to continue the criminal proceeding against this petitioner. If no question of limitation arises the prosecution authority can take necessary steps against the manufacturer. In order to secure ends of justice and to prevent abuse of the process of Court the criminal proceeding against the petitioner requires to be quashed”.

on the 4th September 1928 Honorable Member of the Legislative Assemble of British-India Lieut.-Col. H.A.J.Gidney spoke in the Assemble, “India was par excellence the dumping ground for every variety of quack medicines and adulterated drugs manufactured in all parts of the world and that her markets were gutted with useless and deleterious drugs sold by unqualified chemists, who were themselves a public danger and pleaded strongly for the immediate introduction of a Food and Drugs Act”.¹⁸

Now the point to ponder is whether our Drugs Act succeeded to curb the situation prevailing before its enactment. Government of India has appointed three Committees to assess the situation, Hathi Committee in 1975, Pharmaceutical Committee in 1953 and Mashelkar committee in 2003. All these Committees found that the Drugs Act could not achieve its objective. The Government is also aware of the situation. Print media and Electronics media often highlight the issue. Many attempts have been made by Government of India to make the Drugs and Cosmetics Act and Rules deterrent. In all attempts the Act has been amended and penalty for offender has been enhanced. Last amendment in the Act was made in 2008. Provision of life imprisonment for manufacture or sale of certain adulterated or spurious drug has been introduced. The amount of fine has also been enhanced from few thousand to a million rupees. Enhancing of penalty for various offences under the Drugs and Cosmetics Act and making certain offence Non-bailable is a good step but mere enhancing the punishment will not make the Regulatory provision deterrent.

It is required that some provision in the Act should be incorporated to remove the bottleneck for investigating agencies. There should be provision of nomination of in charge of Factory. This provision is there in Food Adulteration (Prevention) Act 1954 and in Factory Act 1948. There should be an agency for interstate enquiry and investigation. Drugs inspector should have power to interrogate the person who can give information regarding the offence. The Investigating officer should have power to ask a person to make statement regarding his knowledge of offence. In case the person required for interrogation or making statement fails to cooperate the officer may pray in appropriate court for issue of warrant against him. Then only effective Drug Rules will control import, manufacture & sale of substandard, spurious and adulterated drugs in our country.

REFERENCES

1. Times of India, Bhubneswar Edition, 6 June 2011.
2. Punjab and Haryana High Court, Criminal Revision No. 953 of 1982, (20th July 1982).
3. Mashelkar Committee Report 2003, Paragraph 8.4.2.,
4. Supreme Court of India, 1972. Drug Cases 1975: Criminal Appeal 116 of 1969. Decided on 7 March, 34-50 “c”.
5. Allahabad High Court, Drug Cases Cr.App.673/1972.
6. Madras High Court, 1982 Drug Cases, 1982.Criminal Appeal 482 of 1977:Decided On 3rd November 1981.
7. Punjab and Harayana High Court,Criminal Revision No. 755 of 1979 decided on 22nd September,1981,.

8. Madhya Pradesh High Court, 1989. Drug Cases 1999. Miscellaneous Civil Complain, No. 2000 of 1987 Decided on 4th May, 357-63.
9. Patna High Court, 1998. Drug Cases 1999 Criminal Appeal 10291 of 1993. Decided on 11 December, 340-41 "b".
10. Madras High Court, 2002. Drug Cases 2002. Appeal No. 396 of 1998. Decided on 19 March, 311-12.
11. Punjab and Harayana High Court, Criminal Revision No. 30908/1998.
12. Supreme Court of India, Criminal revision No. 579/98.
13. Supreme Court of India, 2001, Drug Cases, 2001: Criminal Appeal 300 of 2001; Decided on 16 March, 168-177 "d".
14. Karnataka High Court, 2002. Drug Cases 2004. Writ Petition No. 40227 of 2003 Decided on 30th March, 2004. 296 "b".
15. Calcutta High Court, C.R.R. No.2863 of 2004, decided on 11th February 2005,
16. Supreme Court of India ,Criminal appeal No.116 of 1969 decided on 7th March 1972, Drug Cases 1975,50.
17. Supreme Court of India, Criminal appeal No.116 of 1969 decided on 7th March 1972, Drug Cases 1975,39.
18. Report of Drugs Enquiry Committee, 1930-31, Government of India Pub., Part I, Section 1 Paragraph 2.
