REPORT NO.
148

PARLIAMENT OF INDIA
RAJYA SABHA

COMMITTEE ON PETITIONS

ONE HUNDRED AND FORTY EIGHTH REPORT

Petition praying to put a check on manufacture of spurious drugs in our country and other related issues

(Presented on 7th February, 2014)

Rajya Sabha Secretariat, New Delhi
February, 2014/Magha, 1935 (Saka)

Website : http//rajyasabha.nic.in
E-Mail:rsc2pet.@sansad.nic.in

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COMPOSITION OF THE COMMITTEE

(2010-11)

1. Shri Bhagat Singh Koshyari ---- *Chairman*

MEMBERS

2. Shri Nandi Yellaiah
3. Shri Avinash Pande
4. Shri Balavant *alias* Bal Apte
5. Shri Rajaram
6. Shri Paul Manoj Pandian
7. Shri Veer Pal Singh Yadav
8. Shri P. Rajeeve
9. Shri Ram Vilas Paswan
10. *vacant*

COMPOSITION OF THE COMMITTEE

(2011-12)

1. Shri Bhagat Singh Koshyari ---- *Chairman*

MEMBERS

2. Shri Nandi Yellaiah
3. Shri Avinash Pande
4. Shri Rajaram
5. Shri Paul Manoj Pandian
6. Shri P. Rajeeve
7. Shri Ram Vilas Paswan
8. Shri Murli Deora
9. Shri V.P. Singh Badnore
10. Shri Darshan Singh Yadav

COMPOSITION OF THE COMMITTEE

(*Re-constituted w.e.f.* 8th *May*, 2013)

1. Shri Bhagat Singh Koshyari ---- *Chairman*

MEMBERS

2. Shri V. P. Singh Badnore
3. Shri Husain Dalwai
4. Dr. Akhilesh Das Gupta
5. Shri Paul Manoj Pandian
6. Shri P. Rajeeve
7. Shri Palvai Govardhan Reddy
*8. Shri Avinash Pande
9. Shri Arvind Kumar Singh
10. Shri A.V. Swamy

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1. Shri Alok Chatterjee, *Joint Secretary*
2. Shri Rakesh Naithani, *Joint Director*
3. Shri Rajendra Tiwari, *Deputy Director*
4. Shri Goutam Kumar, *Assistant Director*
5. Shri Ranajit Chakraborty, *Committee Officer*

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*Nominated *w.e.f.* 22nd July, 2013

INTRODUCTION

I, the Chairman of the Committee on Petitions, having been authorized by the Committee to submit the Report on its behalf, do hereby present this Hundred and Forty-eighth Report of the Committee on the petition signed by Shri Rahul Gaur, r/o Noida (UP) praying to put a check on manufacture of spurious drugs in our country and other related issues (Appendix-I).

2. The petition was admitted by Hon'ble Chairman, Rajya Sabha on 16th December, 2011 under the provisions of Chapter X of the Rules of Procedure and Conduct of Business in Council of States (Rajya Sabha). In accordance with Rule 145 *ibid*, the petition was reported to the Council on 19th December, 2011 by Secretary-General after which it stood referred to the Committee on Petitions for examination and report in terms of Rule 150 *ibid.*

3. The Committee issued a Press Communique inviting suggestions from individuals/organisations on the subject matter of the petition. In response thereto, more than hundred memoranda were received by the Secretariat. The Secretariat scrutinized those memoranda and a gist of the same has been suitably incorporated in the Report.

4. The Committee heard the petitioner on his petition in its sitting held on 21st February, 2012. The Committee heard the Secretaries, Department of Pharmaceuticals (Ministry of Chemicals and Fertilizers) on 1st March, 2012 and Ministry of Health and Family Welfare on 15th June, 2012. The Committee also heard the representatives of selected NGOs/individuals, who had submitted their memoranda on the issues raised in the petition in its sitting held on 16th November, 2012. It considered the draft Report in its sitting held on 17th December, 2013 and adopted the same.

5. The Committee undertook study visits to Hyderabad and Mumbai from 12th to 16th February, 2013 and also Nagpur and Raipur from 3rd to 5th June, 2013 and interacted with various stakeholders including representatives of medical practitioners, drug manufacturer, medical shopkeepers, civil society, social activists, NGOs and respective State Governments represented by the Drug Controllers etc. to see the ground realities of the issues raised in the petition.

6. The Committee while formulating its observations/ recommendations, has relied on the written comments of the concerned Ministries, oral evidence of witnesses, observations of the Members of the Committee and interaction with others.

7. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the Report in separate paragraphs.

New Delhi ;
December 17, 2013
Agrahayana 26, 1935 (*Saka*)

BHAGAT SINGH KOSHYARI
Chairman,
Committee on Petitions
Rajya Sabha

ACRONYMS

UP	–	Uttar Pradesh
R&D	–	Research and Development
WHO	–	World Health Organisation
DCA	–	Drugs and Cosmetics Act
CDSCO	–	Central Drugs Standard Control Organisation
NLEM	–	National List of Essential Medicine
DPCO	–	Drug Price (Control) Order, 1995
NPPA	–	National Pharmaceutical Pricing Authority
PHCs	–	Public Health Centres
NGO	–	Non-Government Organisation
SSI	–	Small Scale Industries
MNCs	–	Multi National Companies
CGHS	–	Central Government Health Scheme
IPC	–	Indian Penal Code
RTGS	–	Real Time Gross Settlement
SMS	–	Short Message Service
GMP	–	Good Manufacturing Practices
GCP	–	Good Clinical Practices

MCI	–	Medical Council of India
NPP	–	National Pharmacovigilance Programme
DCG	–	Drug Controller General
DGHS	–	Director General of Health Services
UTs	–	Union Territories

REPORT

A petition signed by Shri Rahul Gaur, r/o Noida (UP) praying to put a check on manufacture on spurious drug in our country and other related issues was submitted to the Council of States on 19th December, 2011 **(Appendix-I).** The petition essentially relates to the various irregularities and malpractices prevalent in the field of manufacture and marketing of drugs and medicines in our country and the consequential ill effects of these practices on the health of the people of the country including their fleecing by charging exorbitant prices for the drugs they buy. The petition seeks remedial action for the prevailing situation in the interest of the common man.

1.1 While drawing the attention of the Council of States (Rajya Sabha), the petitioner submitted that in India, health services are provided by both the Government and the private Sector. India is emerging as one of the most favoured destinations for collaborative research and developmental bio-informatics and clinical research due to growing compliance with internationally harmonized standards. A number of multinationals have entered the Indian pharmaceutical market due to challenges faced by them globally, like higher healthcare costs, competition from generics, higher R&D costs, etc. India is an attractive global sourcing destination in the segment of bulk drugs, domestic formulation, experts of generics, marketing of patented drugs, contract research and manufacturing and clinical trials. These activities get enormous support in the form of scientific talent and research capabilities and intellectual property protection regime. Following the de-licensing of pharma industry, industrial licensing for most of the drugs and pharma products have been done away with and manufacturers are free to produce any drug which is duly approved by the Drug Control Authority. In the prevailing

regulatory setup, spurious drug industry has, therefore, gained substantial ground in India. According to a WHO estimate, 35% of the world's spurious drugs are produced in India, followed by Nigeria (23%). Moreover, incidence of this menace has increased in the last few years. The fallout of the spread of spurious drugs is devastating on the health of the common man. Re-usage of drugs that have crossed their expiry date and tendency to rope in cheaper substitutes of certain drugs are malpractices that are going on at a fast pace. As per an estimate, market share of spurious drugs constitutes 20% of total drugs market of India (worth nearly Rs. 4000 cr) and increasing tendencies can be seen to carry out the menace further in the form of exporting such drugs to other countries. Poor patients are being subjected to high-risk therapies resulting in severe side effects. On the contrary, the hospitals, pharma companies charge exorbitant price from their principal clients for such services. The hospitals, in addition, also claim tax benefits for such trials. The existing regulatory mechanism provides insufficient check to spurious drug industry which needs to be checked and curbed at any cost.

1.2 In this background the petitioner has made following prayers before the Council of States:-

(i) The spread of spurious drug in the Indian market may be controlled immediately through upgradation of appropriate laws. The recommendations of Dr. Mashelkar Committee, *i.e.,* specifically mentioning spurious drugs an offence under IPC and making the offence non-bailable and cognizable and recommending a maximum of death penalty for this offence may be implemented.

(ii) A system be developed in which doctors prescribe medicines

by their generic name, not by brand name, as is the practice in many developed countries.

(iii) Spread of awareness among the consumers so that they are able to buy correct and proper medicines.

(iv) To put a check on clinical trials more stringently.

(v) Uniform pricing of drugs irrespective of the part of the country in which they are sold and the brand name they carry.

2. The Ministry of Health and Family Welfare, which is the nodal Ministry on the subject matter of the petition in their response has submitted that the Government is aware of the dangers caused by spurious drugs and has taken various steps to check this menace. Stray cases of manufactures and sale of spurious and substandard drugs are detected in different parts of the country by the State Drugs Control Authorities. However, there are no reports of any large scale manufacture of spurious and substandard drugs in the country. The Ministry further submitted that the media had been projecting problem of spurious drugs in the country in a manner which does not provide a balanced perspective and has, therefore, caused serious apprehensions. The Ministry has also submitted the following points for consideration the Committee:-

(i) As per the survey conducted by the Government at the national level in 2009, the extent of spurious drugs found was 0.046% only. The figures emerging in media placing spurious drugs at 10-25% are unsubstantiated.

(ii) The amendment in 2008 in the Drugs and Cosmetics Act (DCA) provides for stringent penalty.

(iii) Central Drugs Standard Control Organisation (CDSCO) has

come out with a whistleblower scheme available on their website.

(iv) Guidelines for taking action on samples of drugs declared spurious in the light of enhanced penalties have been forwarded to State Drug Controllers for implementation.

(v) The inspectorate staff has been instructed to keep proper vigil.

(vi) States/UTs have been requested to set up special court for trials under DCA. 14 States/UTs have already set up such courts.

(vii) The DCA does not mandatorily provide for marketing of drugs under generic names. The Ministry of Health, however, is taking action to promote prescription of medicines by their generic name in the Government run hospitals/medical centers. The Drug Consultative Committee in its 41st meeting held on 28th October, 2010 agreed to the promotion of marketing of drugs under generic names in order to ensure availability of drugs at affordable prices.

(viii) Drug Technical Advisory Board in its meeting dated 26th June, 2011 has agreed to amend the DCA so as to provide the application for grant of license for a drug formulation to contain single active pharmaceutical ingredient in proper name only, thereby promoting manufacture and sale of drugs in their generic name.

(ix) Clinical trials are absolutely necessary for discovery and research. But, a mechanism is in place to check its misuse.

(x) The National Pharma Policy 2006 is at present before the Group of Ministers. A revised National List of Essential Medicines (NLEM) 2011 has recently been sent to the Department of Pharmaceuticals which is examining the possibility of controlling prices of medicines including those covered under NLEM 2011.

2.1 The Department of Pharmaceutical (M/o Chemicals and Fertilizers) is mandated for the issue of pricing of drugs, which forms part of a prayer made by the petitioner. The Department in their written submission has also submitted the following points for consideration of the Committee:-

(i) Prices of 74 drugs and formulations containing any of these scheduled drugs are controlled under the Drug Prices (Control) Order, 1995 (DPCO).

(ii) Prices of drugs not covered under DPCO 1995 are fixed depending upon factors like cost of bulk drug, cost of R&D, cost of utilities, packaging material, margins, quality assurance cost, landed cost of import etc.

(iii) The National Pharmaceutical Pricing Authority (NPPA) is aware of the wide variation in the prices of non-scheduled drugs of different brands based on chemical combination, as there is no control on the launch price of these medicines. The NPPA monitors the movement of these prices on an ongoing basis and under Clause 10(b) of DPCO, 1995, where there is an option for fixing the price of drug formulation in public interest. The NPPA has been able to fix prices in this manner in case of 30 formulations and companies have reduced prices voluntarily in case of 55 formulations as a result of the intervention of NPPA.

Petitioner's oral submission before the Committee (21st February, 2013)

3. The petitioner while deposing before the Committee has made an extensive power point presentation and highlighted that huge networks involved in manufacturing of spurious drugs have evolved over the years. These networks usually include manufacturers, importers, distributors, retailers, inspection agents, shipping agents and official of drug regulatory agencies, custom and police, which are involved in making and marketing of spurious drugs. Manufacturers are free to produce any drug duly approved by the drug controller. Due to the advancement in the technology and relaxation in the norms by the Government, the spurious drug industry has also spread its wings in the country.

3.1 He further submitted before the Committee that reuse of drugs past their expiry date is yet another menace. Filling spurious drugs in used medicine bottles is another *modus operandi*. It was time and again reported in the media that the people in north-eastern states get empty bottles from Bangladesh and refill them with counterfeit drugs and sell them in Indian market. The low-risk, high-return spurious drug industry has been left unattended to grow in our country for a long time.

3.2 Coming to other related issues, the petitioner has submitted that the proposal to promote generic drugs in the country and ensuring their quality has been considered several times by the Government but nothing substantial has come out till date. On the issue of clinical trials, he submitted that the hospitals which claim tax benefits for these trials and pharmaceutical companies charge huge sums from their principal clients for such trials. He then concluded with the prayer that the Mashelkar Committee Report may be implemented fully which recommends that the

offence relating to spurious drugs may be made non-bailable and congnizable and death penalty should be awarded as maximum punishment for those dealing in spurious drugs.

Deposition of Secretary, Department of Pharmaceuticals before the Committee (1st March, 2012)

4. The Secretary outlined the issues raised in the petition specifically in context of the availability of drugs at reasonable prices and of the desired quality so that the poor in the country have access to cheap and quality drugs. He also touched upon the domain of public health and gave a brief on the outline of the constraints in the infrastructure available in the public health system. He gave the example of Tamil Nadu where through a process of a Central Procurement Agency, bulk purchase of medicines is being done in the utmost transparent manner and these medicines are being made available at very competitive prices. He stated that if there is a Central mechanism to procure all the 348 drugs listed under the National List of Essential Medicine (NLEM) through an open transparent tender based system and complemented by a physical infrastructure in the Government facilities like the Public Health Centres (PHCs), it would be feasible to provide affordable medicines to a large section of our population. He also referred to the Drugs Price Control Order (DPCO) and manner in which it was being subverted by our marketing system which is prescription laden and is unscrupulously controlled by chemists and pharmacists.

Deposition of Secretary, Ministry of Health and Family Welfare before the Committee (15th June, 2012)

5. The Secretary categorised the issue of spurious drugs on the three

parameters *i.e.* adulterated drugs, below standard drugs and drugs whose usage date had expired. He mentioned that the new amendments brought about in the Drugs and Cosmetics Act has enhanced the punishment for sellers of spurious drugs. He also outlined the other schemes like the Whistle Blowers Scheme which invited public participation to expose the problems of spurious drugs. He further mentioned that the State Government was enhancing their enforcement machinery despite resource constraints. He outlined the initiative taken by the Ministry on the issues concerning promotion of generic drugs, increasing the National List of Essential Medicines, media campaign to promote the usage of generic drugs and other initiatives being taken up by the Ministry to ensure supply of cheaper medicines. He further outlined the regulatory mechanism governing the issues of clinical trials and mentioned about the entire spectrum of regulatory mechanism which has been established for drugs. He assured the Committee that suitable amendments in the Drugs and Cosmetics Act would be made to ensure ethical and fair mechanisms to establish a system of transparent clinical trials.

5.1 While coming to the quantum of the spurious drugs found in the country, the Secretary submitted that the drug samples tested all over the country in last three years as received from State Drug Controllers, reveals that about 0.2% to 0.3% of around 45,000 samples per annum fall within the category of spurious drugs. Details of number of samples tested declared 'Not of Standard Quality', number of samples declared 'spurious'/'adulterated' in the country since 2006-07 to 2011-12 are as under:-

Sl. No.	Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% of drugs samples declared spurious/ adulterated
1.	2006-07	34738	2024	5.80	78	0.22
2.	2007-08	39117	2429	6.20	77	0.19
3.	2008-09	45145	2597	5.70	157	0.34
4.	2009-10	39248	1942	4.94	117	0.29
5.	2010-11	49682	2372	4.77	95	0.19
6.	2011-12	48082	2186	4.54	133	0.27
7.	April 2012 to July 2012	18262	677	3.70	25	0.13

A statement showing No. of samples tested, No. of Samples declared not of standard quality, No. of samples declared spurious/adulterated, no. of Prosecution launched, No. of persons arrested and approximate value of drugs seized States/UTs - wise during the last three years *i.e.* 2009-10, 2010-11, 2011-12 and from April to July, 2012 as per the information made available by the States/UTs is at **Annexure - II.**

Suggestions/viewpoints of Stakeholders (16 November, 2012)

6. The Committee has received more than hundred memoranda from various organizations/individuals expressing views on the subject matter of the petition. The petition was supported by all organizations/individuals. The Committee gave opportunity to some of the prominent organizations/

individuals to appear before the Committee **(Annexure-I)**. The witnesses submitted their viewpoints one after the other, association-wise. They covered important issues like, sale of spurious drugs in the market, generic drugs, clinical trials, etc. They submitted that the media projects 10% to 25% of drugs in the country as spurious/counterfeit drugs but a study of a sample of drugs tested all over the country in last four to five years reveals that about 0.3% to 0.4% of around 40000 samples fall within the category of spurious drugs. One of the representatives of an NGO stressed upon the awareness of consumers regarding various technique to ascertain quality of drugs, generic drugs and Jan Aushadhi. Another representative submitted that a system needs to be developed in which Doctors prescribe medicines by their generic name, not by their brand name, as is the practice in many developed countries. The views expressed in the memoranda as well as during the oral evidence by witnesses have been summarized and given below:-

(i) Spurious drugs are a shame to the nation and injurious to human life. There should be stringent laws to put some fear in the minds of those who are indulging in this shameful activity.

(ii) To build up the confidence of general public in the Indian Pharmaceutical market as well as industry, Government should come forward and create public awareness about the actual extent of spurious drugs. As per the surveys done by Government of India it is only 0.046% and not 35% as being quoted in the media.

(iii) The Government should pro-actively involve Indian pharma industry including SSI for any policy changes in the regulations.

(iv) The Spurious Drugs Regulation Bill may be further amended to segregate unlicensed criminal elements involved in the trade of spurious drugs and the legitimate licensed manufacturers following the law of the land so that the actual resources and energy of regulatory agencies can be focused on the real criminal elements.

(v) The Drugs and Cosmetics Act, 1940 casts absolute liability to every person engaged in manufacture, sale and distribution of drugs and cosmetics. The absence of *mens rea* {existence of guilty mind} is not considered as defence in trial of offences under the Drugs and Cosmetics Act, 1940. As a result, bonafide mistake committed during the course of routine manufacturing operations and the clandestine/ intentional manufacture of spurious and adulterated drug is placed on the same footing and no distinction is made between the bonafide 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.

(vi) To control the movement of spurious drugs in the market place if any, the provisions of Drugs and Cosmetics Act and the Rules should be strictly implemented. To discourage the purchase of spurious drugs by whole sellers/retailers they should be advised to buy or purchase the drugs on a valid bill and make payment only through a negotiable instrument like cheque/draft etc. In case of investigation by drugs

inspectors/authorities if the purchase bill is not available with the whole sellers/retailers of any drug then he should be asked to produce the same to the authorities within a specified period failing which he should be subjected to heavy penalty or cancellation of license in the event of non-payment.

(vii) Consumers should also be made aware by suitable means to buy medicines only on proper bill/invoice.

(viii) To keep the prices of medicines cheaper in India, the Indian pharmaceutical industry including SSI should get all the support from the Government of India to survive and to face the challenge of big pharma conglomerates of the World, in wake of the change of regulations in patents in the year 2005 whereby now we are following product patent regimen instead of process patent, so now, the new patented molecules the MNCs are launching in the country have no competition what so ever and it is impossible to control their prices as they produce the bulk drugs of these patented molecules out of the country and import at whatever price it suits them.

(ix) A high power committee should be formed including members of associations representing Indian pharma industry to understand all these complex issues that affect the creditability and future of Indian pharma industry and suggest regulatory changes accordingly to safeguard the interest of Indian pharma industry.

x) The patients are becoming bankrupt due to the prescription of highly priced patent branded medicines which are most

often fake and spurious as the doctors are getting a heavy commission in this matter.

(xi) Public by and large is aware of the spurious drugs and also the menace of prescription of highly priced patent branded drugs but is helpless. Even the CGHS (Wellness) Centres under the nose of Ministry of Health and Family Welfare, are buying highly priced patent branded medicines. When Government of India has no control over its dispensaries, how can we expect the private practitioners to restrain from it? A report may be called from all CGHS (Wellness) Centres asking them the amount of money that they have spent on the procurement of highly priced patent branded drugs from the chemists.

(xii) There should be a blanket ban on the purchase of highly priced patent branded drugs in government hospitals, CGHS dispensaries. The power to procure patent branded drugs through local chemists should be withdrawn from all CGHS dispensaries. The dispensaries should only provide generic drugs to the Central Government employees. Central procurement store should buy drugs from the manufacturers and supply them to the CGHS (Wellness) centres of the Central Government. At present, most of the medicines are being purchased through local chemists who provide commission to the doctors of the CGHS dispensaries.

(xiii) An unethical practice in respect of prescribing clinical tests is being done by doctors and no moral compunctions stop them from indulging in this evil practice. The sad feature is

that the tests reports are not even seen by the doctors who prescribe them. Their main motto is to get commission from big pharma companies/ laboratories.

(xiv) There is need for uniform pricing all over the country.

(xv) The menace of fake doctors needs to be eradicated.

Findings of the Committee

7. The Committee has noted that the term 'spurious drugs' has been defined under section 17B of Drugs and Cosmetics Act, 1940 and as amended by the Drugs and Cosmetics (Amendment) Act, 1982. In brief, a drug shall be deemed to be spurious, if it is manufactured under a name which belongs to another, or if it is an imitation of another drug or if it has been substituted wholly or partly by another drug or it wrongly claims to be the product of another manufacturer. The two important parameters of drugs are quality and price. Every nation's agenda is to make available quality medicine at affordable prices to their citizens but we are striving hard to achieve this.

7.1 The Central Government had amended the Drugs & Cosmetics Act, 1940, which is also known as Spurious Drugs Act, with great expectations of curbing the menace of manufacturing and sales of spurious drugs in the country. This illegal business, an organized and nation-wide criminal activity supported by certain powerful vested interests, has been challenging drug control administration in the country for several years in the absence of effective provisions in the D&C Act. Now, a bill amending the D&C Act with some key provisions to eliminate this menace has been passed by the Parliament in November, 2008. The amended law contains stringent provisions such as a maximum penalty of life imprisonment and a fine of not less than Rs. 10 lakh for those engaged

in the manufacturing of spurious drugs. There are similar punishments provided for prosecuting members of the pharmaceutical trade also.

7.2 The amended Act is comprehensive in tackling the menace and the drug inspectors have been given adequate powers to enforce the Act. It has provision of making the offences cognizable and non-bailable. One of the main hurdles faced by state drug control departments has been the inordinate delays in prosecuting the offenders. The provision to have special courts to handle spurious drug cases in the new law is thus very significant and could prove to be a powerful deterrence.

7.3 The Committee understands that the quantum of spurious drugs cannot be merely gauzed through statistical information provided by various States based on analysis of the samples, as the number of samples taken for analysis is miniscule *vis-a-vis* the number of manufacturing units multiplied by the products and number of batches released into the market and the available inspectorate and the capacity to analyze the samples in each States. The Committee identified that mushrooming licenses to manufacture drugs; means of third party products manufacturing; absence of define distribution system; indiscriminately issuance of license to sell drugs; no define tracking system of drugs from manufacturer to ultimate consumer; availability of so many brands; etc. are the causes for the menace of availability of spurious drugs in the market.

7.4 The Committee noted that Dr. R.A. Mashelkar Committee has realized the inadequacies of the enforcement and laboratory wings of the States to curb the menace of spurious drugs effectively and recommended accordingly. But, the Government of India appears to be more focused on the other things *viz.* issue of CDA & licensing systems which has not yield expected results. Dr. R.A. Mashelkar Committee Report emphasized

about providing infrastructure, mobility, interstate co-ordination, vigilance and intelligence sharing among all the States which is still lacking for the want of budgetary support from the States and apathy of Government of India in providing the same.

7.5 The Committee finds the following constraints in enforcement of provisions for providing safe drugs to the public at large and strict monitoring for availability of spurious drugs in different States:-

(i) The onus of monitoring the manufacture, sale and distribution of drugs rests with State Drug Control Authorities.

(ii) The level of enforcement of Drugs and Cosmetics Act in many States has been found to be far from satisfactory.

(iii) The reason for less than satisfactory performance in States are lack of adequate manpower; non-uniformity in implementation of the provisions of the law; lack of adequate infrastructure; varying level of the competence of the regulatory officials etc.

(iv) Strong, professionally managed drugs regulatory system with adequate infrastructure and man power are need of this hour.

(v) The Mashelkar Committee recommended one inspector for 200 sales outlets and one inspector for 50 manufacturing units. Since there are more than 6 lakhs sales outlets licensed in the country and more than ten thousand manufacturing units, 3200 Drug Inspectors are needed in the country to oversee the enforcement of the law.

(vi) Against the required drug inspectors, there are only 1662

sanctioned posts in all States/UTs, and out of which only 1030 posts are filled as per recent data. There is a clear shortage of 2170 Drug Inspectors in the States/UTs.

7.6 The Committee also finds that the spread of use of spurious drugs in the market may also be controlled by introducing appropriate legislative provisions in the related Acts/Laws, implementation of the Mashelkar Committee report which specifically notes the absence of mention of spurious drug offences in the Indian Penal Code (IPC) and recommends that the offences be made non-bailable and cognizable and even recommended death penalty as the maximum punishment for those dealing in spurious drugs.

Observations and recommendations of the Committee

8. The use of spurious drugs in the Indian market is very much evident. Manufacture and sale of spurious drugs is primarily a clandestine activity. Under the provision of Drugs and Cosmetic Act and Rules their under, it is the joint responsibility of Central and State Governments through their respective drugs control organisations to regulate manufacture and sale of drugs as well as to keep surveillance over possible movement of spurious drugs. Spurious drugs are usually manufactured by unlicensed anti social elements but sometimes licensed manufacturers may also be involved. **The Committee feels that any effective action to curb the easy availability of spurious drugs would require continuous surveillance by the regulators and active co-operation from the Law and Order Enforcement machinery in the States. The Committee recommends that the State Drugs Controllers have to keep vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country. The manpower and other infrastructure of the Drugs Control Departments, both at the**

Centre and in the States/UTs need to be strengthened. The Central Drugs Authority needs to be set up which would review the issuance of licenses for manufacture and sale of drugs. Strengthening of existing and creation of new drug testing laboratories is essential to ensure the quality of drugs being produced in India, whether used for domestic distribution or for export to other countries. The Committee also recommends that the Government should ensure dedicated and adequate funding provisions for all these capacity building initiatives to check the menace of spurious drugs.

8.1 **The Committee further recommends for implementation of the Mashelkar Committee report which specifically noted the absence of the mention of spurious drug offences in the Indian Penal Code (IPC) and recommends that the offences be made non-bailable and cognizable, and even recommended death penalty as maximum punishment for those dealing in spurious drugs. The Committee also endorses the recommendation of Mashelkar Committee which holds liable the corrupt Government Officials/ other persons responsible for the same and recommends death penalty as maximum punishment.**

8.2 The Committees is of the view that there is an urgent need to stop the sale of drugs by their commercial nomenclature. The Committee feels that efforts to sell drugs by their generic names have not succeeded. **The Committee therefore recommends that the Drugs and Cosmetic Act needs to be amended to make the sale of medicines under generic names (instead of brand names) mandatory as is being practiced in many developed nations. This single step would result in substantial reduction in prices and would make affordable drugs available to the common man. This would also restrict the malpractices prevalent in the medical profession besides saving a**

huge amount of money which is spent in the form of brand promotion etc. The Committee also recommends that to discourage the purchase of spurious drugs by whole sellers/retailers they should be directed to buy or purchase the drugs on a valid bill and make payment only through a negotiable instrument like cheque/ draft/RTGS transfer etc. In case of investigation by drugs inspectors/authorities, if the purchase bill is not available with the whole sellers/retailers of any drugs then he should be asked to produce the same to the authorities within a specified period failing which he should be subjected to heavy penalty or cancellation of license in the event of non-payment.

8.3 **The Committee recommends that a special logo should be placed at the generic drugs for easy identification of the same by the public at large. The Committee further recommends that all the prescription drugs should carry an authorised number that can authenticate the product. A unique Identification Number along with a bar-code should be printed on the medicine strips to help users to cross-check through an SMS. The Committee also recommends that an intense awareness campaign must be carried out by the Government through print, electronic and social media to spread this valuable information to the general public on a periodic basis.**

8.4 The Committee observes that as per a recent Order of the Supreme Court, the NPPA has to regulate the prices of 348 essential drugs listed in the National List of Essential Medicines (NLEM). Despite the increase in the list of essential medicines which have been brought under the Drug Price Control Order (DPCO) there has hardly been any reduction in the prices of drugs classified under the NLEM. Tinkering with the original salts by adding new molecules in miniscule quantities is being utilised as a common tool to escape the DPCO. New combinations without any

proper research are launched in the market affecting the health of patients besides their high costs. **The Committee strongly recommends that any tinkering with the list of scheduled drugs, non scheduled drugs, basic salts, formulations, their combinations should be permitted to be launched in the market after due diligence and approval from the respective drug controllers of various States. Any new combination should be launched only after its efficacy has been established through proper research and in consultation with the medical council of India. The Committee also recommends for the formation of a committee of experts which monitors the implementation of DPCO besides ensuring that no new combinations are launched by pharma companies at their own behest.**

8.5 The Committee is distressed to note that the mechanism adopted by the Department of Pharmaceuticals in fixing the price upper limit of drugs brought under NLEM takes into account the prices of top selling three brands. This mechanism gives an unnecessary price arbitrage to large and established brands wherein brand establishment has been done through direct and indirect advertisements. Smaller companies having lesser known brand sell the same formulations at one-tenth of the price of branded better known companies. As it is mandatory for all pharma manufacturers to have GMP specifications for their manufacturing units, the Committee feels that there should be no quality difference between medicines sold by smaller manufacturers and bigger players. **The Committee strongly recommends that the cheapest price at which a particular formulation is being sold in the Company should form the basis of fixing price ceiling for drugs under NLEM. The price band be fixed by taking into account the cheapest three brands selling a particular formulation under NLEM instead of just taking the top**

selling brands. This assumes significance keeping in view those sales of drugs is enhanced by getting doctors to prescribe particular brands for which doctors are obliged in one way or the other. The Committee strongly recommends that price band rather than sale be the criteria for fixing pricing under NLEM. The Committee also desires that views of organisations like the All India Drug Action Network be taken into consideration while fixing price ceilings under the DPCO.

8.6 The Committee feels that the fight against spurious drugs is a long drawn war against the illegal trade and the solution depends on the will and competence of the Government authorities. However, the Committee is of the view that the consumers have to play an active role in protecting themselves and help nabbing the culprits. They are required to be vigilant and alert while purchasing and using the drugs. **The Committee recommends that awareness among consumers must be spread to ensure that they buy medicines based on prescriptions of doctors. With many brands with similar sounding names in almost all drug formulations catering to different therapeutic categories, the consumer is not medically educated to make the correct choice. Only a qualified medical practitioner can decide the correct and proper administration of medicine for the particular illness. The patient should be educated to visit the doctor again along with medicine and the prescription to confirm that the right medicine has been purchased.**

8.7 The Committee notes that new drugs need to be invented and to check their efficacy they need to undergo rigorous clinical trials. There is also widespread irregularity in the modus being adopted by the companies wherein poor patients are subjected to high risk therapies resulting in severe side effects. The Committee has been apprised that certain hospitals and

pharmaceutical companies charge huge sums from their principal clients. Hospitals on the one hand usually claim tax benefits for these trials but on the other hand charge huge amounts from their clients. **The Committee therefore recommends that there should be an urgent need to put a check on such clinical trials which is done in the name of research and development for getting tax benefits but the expenses and consequences are borne by the patients on the contrary. It also recommends that all clinical trials, which are necessary, should be registered and inspected by auditors where the maximum number of patients are enrolled. This will ensure that investigators follow Good Clinical Practice (GCP) Guidelines completely. Each investigator should also be certified by Medical Council of India (MCI) to conduct clinical trials by taking their written/online exams. This will make compliance more stringent. The Ethics Committee approvals are integral and necessary. Anybody deliberately violating the Schedule Y requirements and GCP etc. should be penalized and barred from conducting clinical trials in future.**

8.8 The Committee has been given to understand that a National Pharmacovigilance Programme of India was launched on 14 July, 2010 to capture adverse drug reactions data in Indian population, arising out of consumption of spurious drugs, in a systematic way in CDSCO. National Pharmacovigilance programme has been initiated in year 2005 by CDSCO with specific aims to:

(i) Contribute to the regulatory assessment of benefit, harm, effectiveness and risk of medicines encouraging their safe rationale and more effective including cost effective use.

(ii) Improve patient care, and safety in relation to use of medicines, and all medical and para-medical and interventions. Improve public health and safety in relation to use of medicines.

(iii) Promote understanding education and clinical training in Pharmacovigilance and its effective communications to the public. The programme is now coordinated by the Indian Pharmacopeia Commission, Ghaziabad. Currently, 60 medical colleges are functioning as adverse drug reaction monitoring centres. **The committee strongly feels that following two things need to be done to deal with the adverse drug reaction cases:**

(i) **A more comprehensive adverse drug reaction pharmacovigilance monitoring programme than the current National Pharmacovigilance Programme (NPP) should be formulated and should be implemented under capacity building project; and**

(ii) **The adverse drug reaction monitoring should be of high quality done through a special unit manned by experts.**

8.9 The Committee has observed that counterfeit products may include; (i) products with correct ingredients, but containing insufficient or erroneous quantities of active pharmaceutical ingredients, or expired active pharmaceutical ingredients either to save cost or owing to poor quality control factors; (ii) wrong ingredients with possibly toxic elements and impurities and therefore directly harmful to patients; (iii) without active

ingredients or using similar class of cheaper ingredients to escape detection; iv) produced by unhygienic manufacture, or lack of rigorous cleaning between production batches; or v) products with false or misleading packaging. The situation is complicated by the fact that counterfeit drugs often contain active pharmaceutical ingredients, if only because the producers are keen to both avoid detection and generate repeat business. The Committee further notes that the *modus operandi* includes recycling using used vials with intact labels, refilling and re-labelling with packaging similar to branded drugs, imitation, manufacturing without knowledge, reuse beyond expiry date, and large scale counterfeiting.

8.10 The Committee feels that counterfeiting is attractive because relatively small quantities of counterfeit medicines can provide huge profits to the counterfeiter, and is seen to carry less risk than trafficking addictive drugs. The Committee also notes that the problems in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at the State and Centre level, inadequate testing facilities, shortage of drug inspectors, non uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non existence of data bank and non availability of accurate information. In addition the division of labour between the Centre and State regulatory agencies creates inconsistencies in regulatory requirements and policies across the country. Individual States are responsible for licensing and monitoring domestic drug manufacturers for quality and pursuing legal action against offenders. This federal structure means that India lacks national norms for drug quality and that most of the quality policing are done at State level without uniformity of action. This means a manufacturer producing sub standard drugs could receive approval in a State with weak controls and its drugs could be sold anywhere in the country.

8.11 The Committee feels that the wide variation in failure rates among pharmacies suggest that most pharmacists are buying good quality drugs and storing them properly. However, some pharmacists are either buying wittingly or unwittingly substandard drugs, expired drugs that have their packaging possibly restamped with new expiry date or many of the pharmacists are incapable or unwilling to store drugs correctly. **In view of the above, the Committee suggests that more stringent Good Manufacturing Practice (GMP) standards should be followed by drug manufacturers which should be in conformity with international norms while manufacturing at least life saving drugs. A good manufacturing practice makes it mandatory, at par with the international standards for the manufacturers of drugs to comply with the requirements for the schedule for quality control of the drugs manufactured by them.**

8.12 The Committee also feels that the core concept of implementation of deterrent measures with respect to countering the menace of spurious drugs is better coordinated between States as well as the Centre. **The Committee, therefore, further recommends that an all India survey to assess the extent of availability of spurious drugs in the country by drawing samples in a random stratified manner from different regions and different strata in the country on the basis of statistical principles provided by the Indian Statistical Institute should be studied in depth. This would help in identifying the geographical areas where spurious drugs are available so that a focussed monitoring is done by the concerned authorities in these areas for eliminating the menace of spurious drugs.**

8.13 The Committee has been given to understand by the Secretary, Ministry of Health and Family Welfare that whistleblowers scheme has

invited public participation to expose the problems of spurious drugs. **The Committee welcomed such scheme as it felt that there is no dearth of good intentioned people who may wish to work for the country's interests as the whistleblowers in eradicating the menace. People's participation is imperative in this regard and would be a highly effective step in augmenting the efforts of taking on the elements engaged in such illicit trade of spurious drugs.** The Committee has also been given to understand that a scheme has been devised by the Central Government for giving monetary rewards to the whistleblowers who can take risk of providing the information about the perpetrators of such crime. **The Committee strongly recommends for the implementation of such schemes as informed by the Secretary, Ministry of Health and Family Welfare and also hopes that currently a legislation on whistleblowers scheme, which is before the Houses of Parliament, will be passed soon to give sufficient protection to whistleblowers particularly in sensitive cases. The Committee also recommends that the identity of the whistleblower/informer may be kept secret and may be known only to the concerned zonal and sub-zonal officers of the CDSCO, the DCG and the Director General Health Services. It will be the responsibility of the concerned officials to keep the details of the whistleblower/ informer secret.**

8.14 **The Committee would also like to recommend that to ensure speedy trials of the spurious drugs cases, the cases may be filed before the designated/special courts set up for the purposes of drugs related issues as per the provisions of the Drugs and Cosmetics (Amendment) Act, 2008. As the Committee has been given to understand by the Ministry of Health and Family Welfare that 14 States/UTs have already set up special courts for trying spurious drugs cases. The**

Committee hopes that in other States necessary action will be completed by the Ministry to set up special courts for trying drug abuse cases.

8.15 **The Committee recommends that in the case of detection of manufacture and/or sale etc. of spurious or imitation drug products by the unlicensed manufacturers or sellers, the case shall be investigated on top priority. Necessary help from the enforcement agencies like police etc. should also be obtained wherever required so that the rackets are busted and culprits booked in time for taking legal action. The investigations in such cases should be expedited and prosecutions launched at the earliest. The quick and timely investigations would have deterrent effect on the unscrupulous persons.**

8.16 **The Committee strongly recommends that in the case of detection of a case of manufacture and/or sale etc. of spurious drugs by a licensed manufacturer, the case is required to be pursued with equal vigour as in the case of unlicensed manufacturer. In the case of drugs manufactured by a licensed manufacturer under a valid manufacturing licence has been found grossly sub-standard, the matter may be investigated at the manufacturer's end and where it is felt that administrative measures would not be sufficient to meet the ends of justice, the re-course to prosecution should be resorted to. The Committee is also of the opinion that in the case of drugs manufactured by a licensed manufacturer under a valid manufacturing license and found grossly sub-standard and where criminal intent or gross negligence is not established, weapon of prosecution should be used judiciously.**

8.17 **The Committee further recommends that the State Drug Control Departments shall constitute screening committees comprising of at least three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are proposed to be launched. Prosecutions by the inspectors shall be launched on the basis of written permissions of the controlling authority. State Drug Control organisations shall create a rapid alert system so that any vital information in the cases of spurious/adulterated drugs is passed on to the appropriate authorities quickly for taking further action in the matter.**

8.18 **The Committee feels that coordination between regulatory authorities is key to success in taking timely action in cases of violation of the provisions of the drugs and cosmetics rules. The State Drug Control organisations shall therefore notify a nodal officer with telephone and fax numbers at the headquarter as well as circle levels, who could be contacted by other regulatory authorities for exchange of information and coordination in search/ seizures/raid or investigations in the cases of spurious and adulterated drugs.**

8.19 **The Committee feels that for combating the menace of spurious/adulterated drugs a robust infrastructure is essential to implement the provisions of the Drugs and Cosmetics Act. The Drug Control organisations in the States are therefore needed to be strengthened by providing additional manpower, infrastructure, technical capabilities and financial resources for having continuous vigilance about the quality of drugs moving in the market.**

8.20 **The Committee is strongly of the opinion that the Spurious**

Drugs Regulation Bill may be further amended to segregate unlicensed criminal elements involved in the trade of spurious drugs and the legitimate licensed manufacturers following the law of the land so that the actual resources and energy of regulatory agencies can be focused on the real criminal elements.

8.21 **The Committee is also strongly of the opinion that the Drugs and Cosmetics Act, 1940 casts absolute liability to every person engaged in manufacture, sale and distribution of drugs and cosmetics. The absence of *mens rea* {existence of guilty mind} is not considered as defence in trial of offences under the Drugs and Cosmetics Act, 1940. As a result, 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. The Committee therefore strongly recommends amending Section 27 of Act to include *mens rea* cases as in most of the cases where penalties like life imprisonment are there.**

APPENDIX-I

To,

The Council of States
(Rajya Sabha)

The petition of Shri Rahul Gaur

Sheweth

The pharmaceutical industry develops, produces, and markets drugs licensed for use as medications. Pharmaceutical companies are allowed to deal both in generic and brand medications. They are subject to a variety of rules and regulations regarding the patenting, testing and marketing of drugs. In our country, healthcare service is provided both by the Government (public) and private sector. India is one of the top five active pharmaceutical ingredients (API) producers. India is emerging as the most favoured destinations for collaborative Research & Development bioinformatics and clinical research as a result of growing compliance with internationally harmonized standards.

2. A number of multinationals have entered the Indian Pharmaceutical market due to the following challenges faced by the global pharmaceutical industry:

Higher healthcare costs;

Competition from generics;

Patent expiries of blockbuster-drugs; and

Increasing R&D costs.

This offers immense growth opportunity for the Indian Pharmaceutical Industry due to availability of the low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade.

3. India is an attractive global sourcing destination, in the segments of Bulk-drugs, domestic formulations, Exports of generics, marketing of Patented Drugs, Contract Research and Manufacturing and Clinical-Trials. With its rich scientific talents and research capabilities, supported by Intellectual Property Protection regime, the Pharmaceutical Industry in India, is well set to take on the International market. Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with.

Manufacturers are free to produce any drug duly approved by the Drug Control Authority. But due to advancement of technology and relaxation in the norms by the Government, the spurious drug industry is becoming well established in India. According to World Health Organisation's (WHO) 2001 statistics, 35 per cent of the world's spurious drugs are produced in India, followed by Nigeria at 23 per cent. By all accounts the magnitude of this problem would have only increased in the last few years. It has been widely reported in the media that one out of five strips sold in North India is a spurious one.

4. India already shows signs of this industry doing brisk business at the consumers' cost. And its tentacles are spreading far and wide. Unfortunately, consuming a spurious drug unlike buying a counterfeit designer shoes or apparel has mind-boggling ramifications. There is no safe counterfeit. Spurious drugs are life threatening and not life saving drugs. Even when spurious drugs do not endanger life, they can leave

the patient seriously ill and those with inadequate potency do bigger harm to the society in general. Drug resistance develops when patients consume drugs with inadequate potency forcing them to look for costlier new generation drugs. And these patients could put the entire society at risk by spreading drug resistance. Unlike other cases where the consumer knows his intent, the spurious drug industry thrives on consumers' ignorance, lack of stiff penalty for indulging in such activity and finally on lax regulatory system. Packaging is so nearly perfect that distinguishing a spurious drug from a genuine one is almost impossible.

5. Reusage of drugs past their expiry, date is yet another menace. Filling spurious drugs in used medicine bottles is another modus operandi. It was time and again reported in the media that the people in north-eastern states get empty bottles from Bangladesh and refill them with a higher content of narcotics and sell them in Indian market. Cheaper substitutes for biotech drugs are another area of concern. Neupogen for instance is available for nearly half the price. These spurious drugs are made available from across the border. Incidentally, the consequences are not restricted to consumers alone. With a market share of nearly 20 per cent of the total drug market in India (it is worth nearly Rs. 4000 crores) the spurious drug industry's thirst for more is clear to see. It has already set its eye on the export market and succeeded in taking spurious drugs beyond our shores. For instance, Africa and Latin America have taken cognizance of the. increased export of spurious/sub-standard drugs from India and have started complaining about it. And worse, nearly 3-5- per cent of the drugs landing in the U.S. are spurious. The U.S. has already put India in the 301 watch list threat recently. If implemented it would totally ban export of drugs from India and sound the death knell for the Indian drug industry.

6. There is also a widespread irregularity in the modus being adopted by companies wherein poor patients are subjected to high risk therapies resulting in severe side effects by their clinical trials. Hospitals and pharmacy companies charge huge sums from their principal clients. Hospitals on the one hand usually claims tax benefits for these trials but on the other hand charges huge amounts from their clients.

7. The low-risk, high-return spurious drug industry has been left unattended to grow in our country. Though belatedly, the Government is slowly waking up to reality. It plans to advocate death penalty for spurious drug racketing, plans are afloat to reward anyone providing evidence of spurious drug manufacturing or selling, and finally to educate the public about the ills of spurious drugs through the electronic media, but nothing concrete has been done as yet.

8. On the above-mentioned ground realities, the petitioner prayed that:-

(i) The spread of use of spurious drugs in the Indian market may be control by introducing legislative provisions in the related Acts/Laws. Implementation of the Mashelkar Committee report which specifically notes the absence of mention of spurious drug offences in the Indian Penal Code (IPC) and recommends that the offences be made non-bailable and cognizable, and even recommended the death penalty as the maximum punishment for those dealing in spurious drugs;

(ii) Mechanism should be established to prescribe the drugs by their generic name not by their brand by the Doctor as practiced in many developed nations;

(iii) Awareness campaign may be carried out so that consumers

can become more proactive by buying medicines only from reputed and well-established chemists;

(iv) There should be urgent need to put a check on clinical trial which are done for getting tax benefits but on the contrary expenses are borne by the patients; and

(v) Uniform pricing of drugs irrespective of the area in which there sold and brand they are made up off.

Name of the petitioner	Address	Signature
Sh. Rahul Gaur	B-191, Sector-44, Noida-201303	Sd/-

APPENDIX-II

Comments of Ministry of Health and Family Welfare on the petition (*vide* OM No. H. 11013/3/2011-DFQC, dated 29th November, 2011)

1. Stray cases of manufacture and sale of spurious and sub-standard drugs are detected in different parts of the country by the State Drugs Control Authorities. However, there are no reports of any large scale manufacture of spurious and sub-standard drugs in the country. The media had been projecting problem of spurious drugs in the country in a manner which does not provide a balanced perspective and has, therefore, caused serious apprehensions. The figures quoted by media range from 10% to 25% of drugs in the country being spurious. These are unsubstantiated reports. For example, on the basis of an alleged WHO report, the media frequently reported that 35% of fake drugs produced in the world come from India. However, when enquired, the WHO has denied its authenticity.

A survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health, through Central Drugs Standard Control Organisation (CDSCO) on the basis of statistical principles provided by Indian Statistical Institute (ISI), Hyderabad. Under this survey 24,136 samples of 62 brands of drugs belonging to 9 therapeutic categories of 30 manufacturers from over 100 different Pharmacy outlets in different regions of the country and located in each stratum *viz.* metros, big cities, district, towns and villages were collected. The survey has revealed that the extent of drugs found spurious was 0.046% only.

The Government is aware of the dangers caused by the spurious drugs and has taken the following steps to check the menace of spurious drugs:

a. The Drugs and Cosmetics Act, 1940 was amended in 2008. Under this amendment stringent penalties for manufacture of spurious and adulterated drugs are provided. Certain offences are made cognizable and non- bailable. This will have deterrent effect on the manufacture and sale of spurious and sub-standard drugs. The Courts would also now have the liberty of granting higher punishments in view of increased penalties under the Act.

b. Whistle Blower Scheme has been announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The details of policy are available at the website of Central Drugs Standard Control Organisation (CDSCO) (www.cdsco.nic.in).

c. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties were forwarded to the State Drugs Controllers/ State Government for implementation. The guidelines are available on the website of CDSCO (www.cdsco.nic.in).

d. The inspectorate staff has been instructed to keep vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

e. The States/UTs have been requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases. 14 States/UTs have already set up such courts. Ministry is constantly following up with the other States.

f. Overseas inspections of drug manufacturing sites so as to ensure that the foreign manufacturers exporting drugs to India conform to Good Manufacturing Practices.

2. There is no provision under the Drugs and Cosmetics Act and Rules framed thereunder which makes it mandatory that medicines should be marketed under generic names only, without any brand name. Health Ministry has, however, from time-to-time issued directions to doctors in the Central Government-run hospitals to prescribe only generic drugs as far as possible and not branded drugs. Repeated circulars / instructions have been issued to all Government hospitals and CGHS dispensaries to prescribe generic medicines to the maximum extent possible. At the hospitals level also, circulars by Medical Superintendants of hospitals in Delhi have been issued from time to time encouraging / motivating doctors to prescribe generic drugs. Regular meetings are now being taken by Additional DG (Stores) in the Medical Stores Organisation (MSO) with the Government hospitals and CGHS to promote availability and prescription of generic drugs.

The proposal to promote generic drugs in the country and ensuring their quality was considered in the 41st meeting of the Drugs Consultative Committee(DCC) held on 28th October, 2010 at New Delhi. The committee after deliberations agreed that marketing of generic drugs should be promoted in the country while ensuring that they are of comparable standards. DCC recommended that members may grant licences for marketing of single drug formulation in generic name only to promote availability of generic drugs at affordable prices in the country.

In order to facilitate that the drug formulations containing single ingredient should be licensed by the State Licensing Authorities in their proper name, an agenda item to amend the Drugs and Cosmetics Rules

by incorporating the following clause as condition of manufacturing licence was placed before the Drug Technical Advisory Board (DTAB) in its 59th meeting held on 24th June, 2011.

> "Application for grant of licence for a drug formulation containing single active ingredient shall be made in proper name only."
>
> The DTAB has agreed to the proposed amendments.

3. Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 do not differentiate between reputed & well-established Chemists. Sale of medicines by the Chemists has to be strictly under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder.

4. Clinical trials are absolutely necessary for drug discovery and research. The Drugs and Cosmetics Rules, 1945, have provisions for protection of the interest of subjects/patients enrolled in clinical trials. Schedule Y to the said Rules provides requirements and guidelines for permission to undertake clinical trials in the country. Clinical trials of new drugs can be initiated only after approval of Drugs Controller General (India) {DCG(I)} & Ethics Committee. It is provided under the said Schedule that it is the responsibility of the Ethics Committee (EC) that reviews and accords its approval to a trial protocol, to safeguard the rights, safety and well being of all trial subjects. EC(s) should make, at appropriate intervals, an ongoing review of the trials for which they review the protocol(s). Informed written consent is also required to be obtained from the subjects before participation. Investigators are required to ensure that adequate medical care is provided to the participants for any adverse event. Further, Good Clinical Practices (GCP) Guidelines recognised under the said Schedule provides that in cases of trial related injuries or deaths, research subjects who suffer such injury as a result of their

participation in the Clinical Trial are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability subject to confirmation from Ethics Committee. In case of death, their dependents are entitled to material compensation. Various initiatives have been taken for further strengthening of clinical trial regulation to ensure the protection rights, safety and well being of Clinical Trial subjects and authenticity of bio medical data generated. Some of the initiatives are given below:-

a. To improve the transparency and accountability, it has been made mandatory for registration of clinical trials with the Centralized Clinical Trial Registry of ICMR with effect from 15th June 2009.

b. Guidelines for conducting Clinical Trials inspections have been posted on the website of CDSCO (*i.e.* ww.cdsco.nic.in).

c. 12 New Drug Advisory Committees (NDAC) have been constituted to examine the applications for permissions for clinical trials and approvals for new drugs.

d. The Drugs and Cosmetics Act is proposed to be amended to include a separate chapter on Clinical Trials.

e. It is further proposed to make specific provisions under the rules for providing

- Financial compensation to the trial subjects in case of trial related injury or death.
- Enhancement of the responsibilities of Ethics Committee and Sponsor to ensure that financial compensation as well as medical care is provided to

the trial subjects who suffer trial related injury or deaths.

- The format for obtaining informed consent of trial subject to include the details of address and occupation of the subject.

5. The issue of pricing of drugs is the mandate of Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers. The Department of Pharmaceuticals has stated that the National Pharmaceutical Policy, 2006 which is at present before the Group of Ministers has so far held four meetings. The revised National List of Essential Medicines (NLEM), 2011 has recently been sent to the Department of Pharmaceuticals, which is examining all the possibilities of controlling the prices of medicines including those covered under the NLEM, 2011.

APPENDIX-III

F.No. 20(46)/2011/Div.II/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

OFFICE MEMORANDUM

Subject: Petition praying for complete ban on the manufacture of spurious drugs – representation received from Shri Rahul Gaur, Noida received through Rajya Sabha Secretariat.

The undersigned is directed to refer to Department of Pharmaceuticals letter no.31026/2/2011-PI.I dated 14.11.2011 on the above subject and to state that NPPA does not deal with spurious drugs. The issue of prescription of drugs by doctors by generic name and not by their brand is not related to NPPA and is a policy matter which may be dealt by Department of Pharmaceuticals in consultation with Ministry of Health and Family Welfare.

In the case of scheduled drugs, the prices of 74 bulk drugs and the formulations containing any of these scheduled drugs are controlled under the provisions of the Drugs (Prices Control) Order, 1995. NPPA / Govt. fixes or revises prices of scheduled drugs / formulations as per the provisions of the DPCO,1995. No one can sell any scheduled drug / formulation at a price higher than the price fixed by NPPA / Govt. Therefore, there cannot be price variation in cases of scheduled drugs.

In respect of drugs - not covered under the Drugs (Prices Control) Order, 1995 *i.e.* non-scheduled drugs, manufacturers fix the prices by

themselves without seeking the approval of Government / NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities / packing material, trade margins, quality assurance cost, landed cost of imports etc.

NPPA is aware about the wide variation in the prices of non scheduled drugs of different brands based on same chemical combinations as there is no control on the launch price of these medicines. Although the prices of decontrolled drugs are monitored and suitable action is taken by NPPA, as per the guidelines, in cases where price increase is more than 10% in a period of one year, on moving basis. Wide differences in prices of indigenous and imported formulations and between those different brands is a matter of concern which need to be appropriately addressed within the provision of DPCO,1995. Department of Pharmaceuticals may consider framing appropriate guidelines for implementation by NPPA, if considered essential.

As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of IMS Health and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. This is an ongoing process.

Based on monitoring of prices of non-scheduled formulation, NPPA has fixed prices in case of 30 formulation packs under para 10(b) and

companies have reduced price voluntarily in case of 65 formulation packs. Thus in all, prices of 95 packs of non-scheduled drugs have got reduced as a result of the intervention of NPPA.

ANNEXURE-I

List of Organizations/Individuals appeared before the Committe

I. **Federation of Pharma Entrepreneurs (FOPE), Haryana**

1. Shri Umesh Sanghi
2. Shri Rajesh Madan

II. **Indian Drug Manufactures' Association, Mumbai**

1. Shri Vinod Kalani
2. Shri S.K. Arya

III. **Confederation of Indian Pharmaceutical Industry, New Delhi**

1. Shri P.K. Gupta
2. Shri Sudesh Kumar

IV. **All India Organisation of Chemists & Druggists, Mumbai**

1. Shri T.R. Panthri
2. Shri Sandeep Nagia

V. **Consumer Online Foundation, New Delhi**

1. Shri Bejon Kumar Misra
2. Shri Piyush Misra

VI. **Individuals**

1. Shri Ravi Ranjan Singh
2. Dr. Santosh Rai

ANNEXURE-II

Number of samples tested and enforcement actions taken by State Drugs

Controller during 2010-11

Sl. No	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulte-rated	No. of prosecution launched for manu-facturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approximate value of drugs seized (In Laks.)
1	2	3	4	5	6	7	8	9
1	Andhra Pradesh	4052	52	1	1	Nil	Nil	0.004
2	Arunachal Pradesh	2	Nil	Nil	Nil	Nil	Nil	Nii
3	Assam	760	63	1	1	Nil	Nil	0.959

1	2	3	4	5	6	7	8	9
4	Bihar	2359	58	8	39	Nil	24	22.90
5	Goa	642	26	Nil	1	Nil	Nil	Nil
6	Gujarat	5037	317	6	17	6	Nil	Nil
7	Haryana	2348	67	1	4	Nil	Nil	Nil
8	Himachal Pradesh	1125	17	Nil	Nil	Nil	Nil	Nil
9	Jammu & Kashmir	1480	27	4	3	Nil	Nil	12.467
10	Karnataka	3740	136	5	2	Nil	4	1.072
11	Kerala	3485	128	Nil	36	Nil	Nil	Nil
12	Madhya Pradesh	1936	82	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	6494	449	31	3	Nil	2	9.400
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	157	1	Nil	I	Nil	Nil	Nil
16	Mizoram	86	3	Nil	Nil	Nil	Nil	Nil

17	Nagaland	63	0	Nil	Nil	Nil	Nil	Nil
18	Orissa	3166	111	Nil	2	Nil	Nil	Nil
19	Punjab	2864	60	Nil	Nil	Nil	Nil	Nil
20	Rajasthan	2315	133	4	4	Nil	2	9.671
21	Sikkim	24	4	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	3632	284	3	6	Nil	38	1.350
23	Tripura	518	19	Nil	Nil	Nil	Nil	Nil
24	Uttar Pradesh	1247	179	30	38	2	1	Nil
25	West Bengal	917	39	Nil	Nil	Nil	Nil	Nil
26	Pondicherry	Nil	0	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	11	5	Nil	Nil	Nil	Nil	1.648
28	Chandigarh	33	3	Nil	Nil	Nil	Nil	Nil
29	Delhi	651	24	Nil	1	Nil	1	0.140
30	Dadra & Nagar Haveli	10	Nil	1	1	Nil	Nil	55.000

1	2	3	4	5	6	7	8	9
31	Daman & Diu	49	1	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	0	Nil	Nil	Nil	Nil	Nil
33	Chhattisgarh	182	67	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	195	16	Nil	7	Nil	Nil	6.608
35	Uttaranchal	102	1	Nil	Nil	1	Nil	Nil
	Total	49682	2372	95	167	9	72	121.218
		100%	4.77%	0.19%	0.33%	0.02%	0.14%	

[MINUTES OF THE MEETING OF THE COMMITTEE ON PETITIONS]

XXIV

TWENTY FOURTH MEETING

The Committee met at 12.00 Noon on Tuesday, the 21st February, 2012 in Room No. 63, First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

1. Shri Bhagat Singh Koshyari - *Chairman*
2. Shri Avinash Pande
3. Shri Rajaram
4. Shri Paul Manoj Pandian
5. Shri Veer Pal Singh Yadav
6. Shri Ram Vilas Paswan

SECRETARIAT

1. Shri Deepak Goyal, *Joint Secretary*
2. Shri Rakesh Naithani, *Joint Director*
3. Shri Ashok K. Sahoo, *Deputy Director*
4. Shri Goutam Kumar, *Assistant Director*

WITNESSES

1. Shri Rahul Gaur, Petitioner

2. Ms. Navneet Bhadla

3. Dr. Mira Siva

2.1 The Chairman welcomed the Members of the Committee and informed them about the agenda for the day *i.e.* recording of oral evidence of the petitioner and others on the petition praying to put a check on manufacture of spurious drugs in our country. In his opening remarks, he summarised the main contention of the petitioner in the petition which says that India is an attractive global sourcing destination in the segment of bulk drugs, domestic formulation, exports of generics, marketing of patented drugs, contract research and manufacturing, and clinical trials. These activities get enormous support in the form of scientific talent and research capabilities and intellectual property protection regime. De-licensing of pharma industry, industrial licensing for most of the drugs and pharma products have been done away with and manufacturers are free to produce any drug which is duly approved by the Drug Control Authority. He has also pointed out that as per petition, the World Health Organization's (WHO) estimates that 35% of the world's spurious drugs are produced in India. He also highlighted the issue of re-usage of drugs that have crossed their expiry date and tendency to rope in cheaper substitutes of certain drugs.

3. The petitioner made an extensive power point presentation and highlighted that there is huge network involved in manufacturing spurious drugs have evolved over the years. These networks usually include manufacturers, importers, distributors, retailers, inspection agents, shipping agents and official of drug regulatory agencies, custom and police, which are involved in making and marketing of spurious drugs. Manufacturers are free to produce any drug duly approved by the drug

controller. Due to the advancement in technology and relaxation in the norms by the Government, the spurious drug industry has also spread its wings in the country.

3.1 He further submitted that reuse of drugs past their expiry date is yet another menace. Filling spurious drugs in used medicine bottles is another *modus operandi*. It was time and again reported in the media that the people in north-eastern states get empty bottles from Bangladesh and refill them with counterfeit drugs and sell them in Indian market. The low-risk, high-return spurious drug industry has been left unattended to grow in our country for a long time.

3.2 Coming to other related issues, the petitioner has submitted that the proposal to promote generic drugs in the country and ensuring their quality has been considered several times by the Government but nothing substantial has come out till date. On the issue of clinical trial, he submitted that the hospitals and pharmaceutical companies charge huge sums from their principal clients for such trials. Hospitals on the one hand usually claims tax benefits for these trials but on the other hand charge huge amounts from their clients. He then concluded with the prayer that the Mashelkar Committee Report may be implemented fully which recommends that the offence relating to spurious drugs may be made non-bailable and congnizable and death penalty should be awarded as maximum punishment for those dealing in spurious drugs.

4. One Member who came alongwith the petitioner has submitted that there is problem of non-essential, irrational, hazardous drugs alongwith the spurious drugs in our country. She emphasized to have a National Drugs Policy as well as a National Health Policy put in place to check the menace of health related issues in the country.

5. Some of the members were asked some queries which were satisfactorily answered by the petitioner and others.

(Witnesses then withdrew)

6. A verbatim record of the proceedings of the meeting was kept.

7. The meeting, thereafter, adjourned at 12.57 P.M.

XXV
TWENTY FIFTH MEETING

The Committee met at 3.00 P.M. on Thursday, the 1st March, 2012 in Committee Room 'E', Basement, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Ram Vilas Paswan --- *In the Chair*
2. Shri Nandi Yellaiah
3. Shri Avinash Pande
4. Shri Rajaram
5. Shri Paul Manoj Pandian
6. Shri P. Rajeeve

SECRETARIAT

1. Shri Deepak Goyal, *Joint Secretary*
2. Shri Rakesh Naithani, *Joint Director*
3. Shri Ashok K. Sahoo, *Deputy Director*
4. Shri Goutam Kumar, *Assistant Director*

Representatives of Department of Pharmaceuticals (M/o Chemicals and Fertilizers)

1. Shri D. S. Kalha, Secretary
2. Dr. Raja Sekhar Vunduru, Addl. Secretary
3. Shri Om Prakash, Member Secretary (NPPA)

2. In the absence of the Chairman, Shri Ram Vilas Paswan was voted to the Chair.

3. The Chairman welcomed the Members of the Committee and informed them about the agenda for the day *i.e.* recording of oral evidence of Secretary, Department of Pharmaceuticals (Ministry of Chemicals & Fertilizers) on the petition praying to put a check on manufacture of spurious drugs in our country and other related issues. He, in his opening remarks, stated that implementing uniform pricing of drugs irrespective of the area in which they are sold and the brand there are made up of is the need of the hour. The Chairman invited the Secretary, Department of Pharmaceuticals to start his presentation on the issues raised in the petition and desired to know the initiatives taken by the Department of Pharmaceuticals which ensure easy availability of good quality pharmaceuticals of mass consumption at reasonable prices.

4. The Secretary outlined the issues raised in the petition specifically in context of the availability of drugs at reasonable prices and of the desired quality so that the poor in the country have access to cheap and quality drugs. He also touched upon the domain of public health and gave a brief of the outline of the constraints in the infrastructure available in the public health system. He gave the example of Tamil Nadu were through a process of a Central Procurement Agency, bulk purchase of medicines is being done in the utmost transparent manner and these medicines are being made available at very competitive prices. He stated that if there is a Central mechanism to procure all the 348 drugs listed under the National List of Essential Medicine (NLEM) through an open transparent tender based system and complemented by a physical infrastructure in the Government facilities like the Public Health Centres (PHCs), it would be feasible to provide affordable medicines to a large section of our population. He also referred to the Drugs Price Control Order (DPCO) and manner in which it was being subverted by our

marketing system which is prescription laden and is controlled by chemists and pharmacists. The Secretary further gave a detailed analysis of the pharma scenario in the country and outlined the provisions needed to address the systemic failures and lacunas.

5. Few Members raised certain queries regarding the NLEM, DPCO, Generic drugs, Health Budget and other related issues. The queries were suitably addressed by the Secretary.

(The witnesses then withdrew)

6. A verbatim record of the proceedings of the meeting was kept.

7. The meeting, thereafter, adjourned at 4.25 P.M.

XXVIII
TWENTY EIGHTH MEETING

The Committee met at 3.00 P.M on Friday, the 15th June, 2012 in Main Committee Room , Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Bhagat Singh Koshyari - *Chairman*
2. Shri Avinash Pande
3. Shri Rajaram
4. Shri Paul Manoj Pandian
5. Shri P. Rajeeve
6. Shri Ram Vilas Paswan

SECRETARIAT

1. Shri Deepak Goyal, *Joint Secretary*
2. Shri Rakesh Naithani, *Joint Director*
3. Shri Ashok K. Sahoo, *Deputy Director*
4. Shri Goutam Kumar, *Assistant Director*

Representatives of Ministry of Health and Family Welfare on the petition praying to put a check on manufacture of spurious drugs in our country and other related issues:

1. Shri P.K. Pradhan, Secretary
2. Shri L.C. Goyal, AS & DG

3. Shri Sanjay Prasad, Director

4. Dr. G.N Singh, DCG (I)

5. Shir A.K. Pradhan, Asst. DCG (I)

2. At the outset, the Chairman welcomed Members and informed them that as per today's agenda, the Committee would record the oral evidence of the Secretary, Ministry of Health and Family Welfare on the petition praying to put a check on manufacture of spurious drugs in our country and other related issues. The Chairman in his opening remarks, stated that we need to put a check on manufacturing of spurious drugs immediately through upgradation of appropriate laws; implementation of recommendations of Dr. Mashelkar Committee and other appropriate steps keeping in view the ever increasing menace of spurious drugs. The Chairman then invited the Secretary, Ministry of Health of Family welfare to present his views on the Petition.

3. The Secretary categorised the issue of spurious drugs on the following parameters *i.e.* adulterated drugs, below standard drugs and drugs whose usage date had expired. He further mentioned that the new amendments brought about in the Drugs and Costmetics Act have enhanced the punishment for sellers of spurious drugs. He also outlined the other schemes like the Whistle Blowers Scheme which invited public participation to expose the problems of spurious drugs. He further mentioned that the State Government were enhancing their enforcement machinery despite resource constriants. He further outlined the initiative taken by the Ministry on the issues concerning promotion of genric drugs, increasing the National List Essential Medicines, media campaign to promote the usage of genric drugs and other initiatives being taken up by the Ministry to ensure supply of cheaper medicines. He also outlined the

regulatory mechanism governing the issues of clinical trials and mentioned about the entire spectrum of regulatory mechanism which has been established for drugs. He also assured the Committee that suitable amendments in the Drugs and Cosmetics Act would be made to ensure ethicial and fair mechanisms to established a system of trasparent clinical trials.

3.1 Few members raised certain queries regarding quality of drugs, clinical trials, genric drugs and the efficacy of the drugs enforcement machinery. The queries were suitably addressed by the Secretary.

(Witnesses then withdrew)

4. A verbatim record of the proceedings of the meeting was kept. The meeting, thereafter, adjourned at 4.01 P.M.

XXXVI
THIRTY SIXTH MEETING

The Committee met at 11.00 A.M. on Friday, 16th November, 2012 in Main Committee Room , Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Bhagat Singh Koshyari - *Chairman*
2. Shri Nandi Yellaiah
3. Shri Avinash Pande
4. Shri P. Rajeeve
5. Shri Ram Vilas Paswan
6. Shri V.P. Singh Badnore
7. Shri Darshan Singh Yadav

SECRETARIAT

1. Shri Deepak Goyal, *Joint Secretary*
2. Shri Rakesh Naithani, *Joint Director*
3. Shri R.P. Tiwari, *Deputy Director*
4. Shri Goutam Kumar, *Assistant Director*

List of representatives of NGOs and individuals on the petition praying to put a check on manufacture of spurious drugs in our country and other related issues:

I. **Federation of Pharma Entrepreneurs (FOPE), Gurgaon, Haryana**

1. Shri Umesh Sanghi
2. Shri Rajesh Madan

II. **Indian Drug Manufactures' Association, Worli, Mumbai**

1. Shri Vinod Kalani
2. Shri S.K. Arya

III. **Confederation of Indian Pharmaceutical Industry (SSI) (Regd.), Vikaspuri, New Delhi**

1. Shri P.K. Gupta
2. Shri Sudesh Kumar

IV. **All India Organisation of Chemists & Druggists (AIOCD), Dadar (W), Mumbai**

1. Shri T.R. Panthri
2. Shri Sandeep Nagia

V. **Consumer Online foundation, East of Kailash, New Delhi**

1. Shri Bejon Kumar Misra
2. Shri Piyush Misra

VI. **Individual Representatives**

1. Shri Ravi Ranjan Singh, Delhi
2. Dr. Santosh Rai, New Delhi

2. At the outset, the Chairman welcomed Members of the Committee to the sitting convened to record evidence of the representatives of certain Associations/NGOs and individuals who have submitted their memoranda

on the petition praying to put a check on manufacture of spurious drugs in our country and other related issues in response to the press release issued by the Committee. The Chairman in his opening remarks stated that to curb the menace of spurious drugs, implementing of uniform pricing of drugs irrespective of the area in which they are sold and the brand they carry is the need of the hour. He also stated that proposal to promote generic drugs in the country and ensuring their quality has been considered several times by the Government but nothing substantial has been done in this regard, as yet.

3. The witnesses submitted their view points one after the other, association-wise. They covered important issues like, sale of spurious drugs in the market, generic drugs, clinical trials, etc. They submitted that the figures quoted by media rate 10% to 25% of drugs in the country as spurious/counterfeit drugs but a study of a sample of drugs tested all over the country in last four to five years reveals that about 0.3% to 0.4% of around 40000 samples fall within the category of spurious drugs. One of the representatives of an NGO stressed upon the awareness of consumers regarding various technics to ascertain quality of drugs, generic drugs and Jan Aushadhi. Another representative submitted that a system needs to be developed in which Doctors prescribe medicines by their generic name, not by their brand name, as is the practice in many developed countries.

(The witnesses then withdrew)

4. A verbatim record of the proceedings of the meeting was kept.

5. The meeting, thereafter, adjourned at 12.26 P.M

XIII
THIRTEENTH MEETING

The Committee met at 10.30 A.M. on Tuesday, the 17th December, 2013 in Room No. 126 -A (Chairman's Room), 3rd Floor, Parliament House, New Delhi.

MEMBERS PRESENT

1. Shri Bhagat Singh Koshyari - *Chairman*
2. Shri Hussain Dalwai
3. Shri Arvind Kumar Singh
4. Shri A.V. Swamy
5. Shri Avinash Pande
6. Shri P. Rajeeve

SECRETARIAT

1. Shri Alok Chatterjee, *Joint Secretary*
2. Shri Rakesh Naithani, *Joint Director*
3. Shri Rajendra Tiwari, *Deputy Director*
4. MembersShri Goutam Kumar, *Assistant Director*
5. Shri Ranajit Chakraborty, *Committee Officer*

2. The Committee took up for consideration its draft Hundred and Forty-eighth Report on petition praying to put a check on manufacture of

spurious drugs in our country and other related issues ***and adopted both the Reports with minor modifications.

3. The Committee authorised its Chairman and in his absence Shri P. Rajeeve to present the Report to the Rajya Sabha on Thursday, the 19th December, 2013.

4. * * *

5. The meeting, thereafter, adjourned at 10.55 A.M.

***Relate to some other matters.