



# **EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

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Based on  
A SURVEY ON THE EXTENT OF SPURIOUS (COUNTERFEIT)  
MEDICINES IN INDIA

**31 May 2007, New Delhi, India**

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Prafull D Sheth  
M. V. Siva Prasada Reddy  
**SEARPharm Forum**

Brijesh Regal  
Madhulika Kaushal  
Kaustav Sen  
**Apothecaries Foundation**

D. B. A. Narayana  
**Delhi Pharmaceutical Trust**

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**SEARPharm Forum Secretariat**  
E-256, Greater Kailash - I, New Delhi - 110 048  
Telefax: +91-11-4163 2089, 4656 6411  
E-mail: [searpharmforum@hotmail.com](mailto:searpharmforum@hotmail.com)  
Website: [www.searpharmforum.org](http://www.searpharmforum.org)

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## 1. GLOSSARY OF TERMS

**1.1 ESTIMATE:** Scientific approximation of the extent of spurious medicines, based on findings of the study conducted and reported here.

**1.2 LOCATIONS OF INTEREST:** Locations of interest (LoI) for this study are those places (metro cities, cities, district head quarters etc.) where the incidence and prevalence of spurious drugs has been perceived to be relatively higher.

**1.3 RETAIL DRUG STORES/MEDICAL STORE/CHEMIST SHOP/PHARMACY:** Those retail outlets that have been licensed by respective State Licensing Authorities to sell medicines (drugs) by retail.

**1.4 CHEMIST/ PHARMACIST:** Qualified and experienced persons licensed by State Pharmacy Councils to dispense and sale medicines.

**1.5 SPURIOUS DRUGS:** The term “spurious” is loosely equivalent to the term “counterfeit”. However, this study is being based on the relevant portion of the definition of Spurious drugs as provided in Section 17-B of the Drugs and Cosmetics Act, 1940 of Government of India.

**1.5.1** For the purpose of the study, a medicine (drug) has been deemed to be spurious if

**1.5.1.1** the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or [Rule 17-B(c)]

**1.5.1.2** it purports to be the product of a manufacturer of whom it is not truly a product [Rule 17-B(e)]

**1.5.1.3** it is manufactured under a name which belongs to another drug / substance; or [Rule 17-B(a)]

**1.5.2** For the purpose of this study, the expression Spurious drugs does *not* include any drug:

**1.5.2.1** if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or [Rule 17-B(b)].

**1.5.2.2** if it has been substituted wholly or in part by another drug or substance [Rule 17-B(d)]

**1.5.3** The term, 'counterfeit' that is commonly used worldwide for spurious drug does not appear in Drugs and Cosmetic Act but, the above definition of spurious drug comprehensively covers counterfeit drug also.

**1.5.4** A drug is considered 'Not of standard quality' or substandard if it fails to comply with any of the parameters of the overall standards laid down for it either in a recognized pharmacopoeia or otherwise pre declared by the manufacturer.

**1.5.5** A Spurious drug may or may not have ingredients with therapeutic use while Counterfeit drug may comply with quality standard while imitating popular brands.

**1.5.6 COUNTERFEIT SUSPECTS:** For the purpose of this study, abnormalities found during visual inspection is the first inference of differences in packaging or product manufactured by the same manufacturer. Such samples are classified as 'counterfeit suspects' pending verification and confirmation by the manufacturer as counterfeits or otherwise.

**1.5.7** For the purpose of this study, the terms drug, medicine, pharmaceutical product and pharmaceuticals are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic or therapeutic use.

**1.6 SAMPLE:** The term “sample” in this study refers to single unit of packaging, such as, a strip or blister pack of tablet or capsules, a tube of ointment or cream or gel, a bottle of syrup, a vial or ampoule of injection.

## 2. ABBREVIATIONS

<b>2.1</b>	<b>AF</b>	Apothecaries Foundation
<b>2.2</b>	<b>CVDs</b>	Cardio Vascular Drugs
<b>2.3</b>	<b>DPT</b>	Delhi Pharmaceutical Trust
<b>2.4</b>	<b>FIP</b>	International Pharmaceutical Federation
<b>2.5</b>	<b>MoH</b>	Ministry of Health
<b>2.6</b>	<b>NABL</b>	National Accreditation Board for Testing and Calibration Laboratories
<b>2.7</b>	<b>NSAIDs</b>	Non steroidal Anti-inflammatory Drugs
<b>2.8</b>	<b>PA</b>	Professional Associate
<b>2.9</b>	<b>SOP</b>	Standard Operating Procedure
<b>2.10</b>	<b>SEARPharm Forum</b>	FIP-WHO Forum of National Pharmaceutical Associations in South East Asia Region
<b>2.11</b>	<b>TB</b>	Tuberculosis
<b>2.12</b>	<b>WHO</b>	World Health Organization
<b>2.13</b>	<b>WHO-SEARO</b>	World Health Organization - South East Asian Regional Office

### 3. INTRODUCTION

**3.1** At the World Health Assembly in May 1988, many countries expressed concern about counterfeit drugs circulating in their markets. The assembly adopted a resolution, which requested the governments and pharmaceutical manufacturers to cooperate in the detection and prevention of falsely labelled, spurious, counterfeit or substandard drugs. The prevalence of counterfeit drugs has been reported from developed as well as developing countries but there is no accurate data available on the extent of this problem.

**3.2** Counterfeiting of pharmaceuticals and the proliferation of substandard drugs has been a serious concern for the population of the world.

**3.2.1** Although, counterfeited pharmaceutical products belonging to almost all therapeutic classes have been found, however, counterfeit anti-infectives is a wide spread problem.

**3.2.2** With the advent of the information technology, drug counterfeiting is becoming more and more sophisticated. Counterfeit drugs are imported, smuggled or manufactured locally by consortia in large factories and establishments equipped with the most modern equipments, as well as by small-time operators in smaller, often poorly equipped facilities.

**3.2.3** Present day complexities in the distribution systems lend themselves to several entry points for counterfeit drugs into the system. Very often the products are bought and sold at five or six or even more times by Carry and Forwarding (C&F) agents, whole-sellers, stockists, sub-stockists etc. before they reach a retail pharmacy and eventually the patient. Understandably, this secondary market is particularly vulnerable to unscrupulous endeavours of unethical traders and criminals. Illegally imported, stolen, counterfeit or adulterated drugs have an easier access to the distribution system through the

secondary market. On top of this, the free availability of drugs without prescription has also lead to proliferation of counterfeit drugs.

**3.2.4** Some examples of types of counterfeit drugs include:

**3.2.4.1** Products which do not contain any of the specified active ingredients despite such declarations on their labels.

**3.2.4.2** Products which contain active ingredients other than specified on their labels.

**3.2.4.3** Products which contain the correct strength of the specified active ingredients but whose source is different to the one declared.

**3.2.4.4** Products which contain the specified active ingredients but in strengths different to those declared; they may also contain different or different quantities of impurities.

**3.3** Although various estimates have been made about the extent of spurious drugs in India - no systematic study has ever been undertaken to generate any credible data. Indian Government's own estimates between 1995-2003, for the extent of spurious drugs vary between 0.24 to 0.47 per cent, and for substandard drugs from 8.19 to 10.64 per cent (Table 1). However, various reports peg the extent of spurious drugs in India at around Rs. 4000 crores (\* US\$ 1000 million). However, since the issue of spurious drugs has immense public health as well as business connotations - the lack of credible data has led to various speculative and magnified figures in press.

**Table1:** A statement indicating number of samples tested by government labs, found substandard/spurious during the period of 1995-2003

Year	Tested	Not of standard quality	Spurious	Not of standard quality %	Spurious %
1995-1996	32,770	3490	100	10.64	0.30
1996-1997	30,936	3189	94	8.19	0.24
1997-1998	32,936	2979	157	9.04	0.47
1998-1999	38,936	3189	94	8.19	0.24
1999-2000	35,570	3666	115	10.31	0.32
2000-2001	36,947	3088	112	8.36	0.30
2001-2002	38,824	3458	96	8.96	0.25
2002-2003	36,314	3395	125	9.34	0.34

**Source:** *A report of the Expert Committee on "A comprehensive examination of drug regulatory issues, including the problem of spurious drugs", MoH, Government of India, November 2003*

**3.4** The issue of counterfeit drugs is invariably debated with emotive concern rather than a factual understanding of the situation. The very fact that it is a matter of serious concern, particularly since it relates to all sections of the society, it is an imperative need to quantify the problem and then device strategies appropriate to the extent of counterfeiting. This study is aimed to scientifically explore and comprehend the information through a logical model to collect and analyze the data statistically, and then to extrapolate the data to get a clearer understanding of the extent of the problem across entire country.

**3.5** In November 2003, an expert committee, appointed by MoH under the Chairmanship of Dr. R.A. Mashelkar, carried out a comprehensive examination

of drug regulatory issues, including the problem of spurious drugs in India. The Committee opined that there was an absence of a scientific and statistically designed investigation. The Delhi Pharmaceutical Trust (DPT) was invited by the Committee to present a protocol for an objective estimation of spurious drugs in the country. Upon review of DPT's proposal, the Committee recommended that the MoH should undertake a study based on such a scientific and statistical model to obtain a clearer picture on the extent of spurious drugs in India. Subsequently, WHO- SEARO invited SEARPharm Forum to conduct such a study. SEARPharm Forum with the technical assistance of Apothecaries Foundation which had conceptualized the study model and prepared the protocol conducted the study. SEARPharm Forum provided the oversight of the study conduct and managed the interface between, Apothecaries Foundation and WHO-SEARO.

## 4. STUDY OBJECTIVES

### 4.1 PRIMARY OBJECTIVE

4.1.1 To study the extent of spurious drugs in India

### 4.2 SECONDARY OBJECTIVE

4.2.1 To identify the most and least affected therapeutic drug segments

4.2.2 To identify the most and least affected region, states and cities in the country

### 4.3 THE STUDY ADDRESSED THE FOLLOWING IMPORTANT ISSUES

4.3.1 Extent of the spurious drug prevalence in India

4.3.2 Relative prevalence of spurious drugs in various states and regions

4.3.3 Estimation of approximate volume and percentage (%) of spurious drugs available through retail drug stores

4.3.4 Prevalence of spurious drugs in various identified therapeutic segments

4.3.5 Estimation of the extent of spurious drugs in the identified cost segments

4.3.6 Estimation of the extent of spurious drugs in metro/major cities and district headquarters

### 4.4 THE STUDY WAS NOT MEANT TO ADDRESS THE FOLLOWING ISSUES

4.4.1 Extent of spurious drugs exported from India

4.4.2 Extent of spurious drugs circulating in inter-country commerce

4.4.3 Extent of spurious drugs prevailing in other than retail sale channels

4.4.4 Extent of spurious drugs prevailing in small towns and rural areas

4.4.5 Extent of spurious drugs of brands of relatively smaller manufacturers

4.4.5 Extent of spurious drugs of relatively low sales turnover products

Above categories must be covered in a separate study, to obtain a more comprehensive picture of the situation.

## 5. METHODOLOGY

### 5.1. STUDY DESIGN

**5.1.1** The study has been based on stratified multistage sampling, and has been designed on the basis of selection and classification of the Locations of Interest (LoI) for sample collection and therapeutic categories as well as cost of the drugs.

**5.1.1.2 Selection of LoIs:** The Locations of Interest across the country were decided on the basis of perception of how efficiently they are regulated by the state/central government's drug regulatory authorities, as classified in Table 2.

**Table 2:** Category of states perceived to be strong, medium and weak based on regulatory enforcement

Category A (Perceived strong regulatory enforcement states)	Category B (Perceived medium regulatory enforcement states)	Category C (Perceived weak regulatory enforcement states)
Maharashtra, Delhi (NCT), Karnataka, Gujarat and Goa	West Bengal, Tamil Nadu, Orissa, Andhra Pradesh	Uttar Pradesh, Madhya Pradesh, Haryana, Bihar, Assam, Rajasthan and Punjab

LoIs under each category were further divided region wise into major cities and district headquarters in states

**Table 3:** Location of Interest under each region and state

S.No.	Region	State	Lol: Metro/major city/ district
1	North	NCT Delhi, U.P., Rajasthan, Haryana and Punjab	AIIMS, Bhagirath Palace, Dwarka (all in Delhi), Ghaziabad, Meerut, Agra, Gorakhpur, Jaipur, Bhiwadi, Karnal, Panipat, Jalandhar and Ludhiana
2	South	Tamil Nadu, Karnataka & Andhra Pradesh	Chennai, Thanjavur, Madurai, Shimoga, Bangalore, Hyderabad, Guntur and Vijaywada
3	East	West Bengal, Orissa, Bihar	Kolkata, Midnapur, Bhubaneshwar, Sambalpur, Bhawanipatna, Patna and Muzaffarpur
4	West	Maharashtra, Gujarat, Goa	Nagpur, Princess Street (Mumbai), Amdavad, Vadodara and Panaji
5	Central	Madhya Pradesh	Indore and Morena

## 5.2 THERAPEUTIC CATEGORIES

**5.2.1** Following therapeutic categories of drugs have been included in this study:

- 5.2.1.1** Anti-infectives
- 5.2.1.2** Steroids
- 5.2.1.3** Antihistamines
- 5.2.1.4** Cardio Vascular Drugs
- 5.2.1.5** Anti-diabetics
- 5.2.1.6** NSAIDs
- 5.2.1.7** Anti-malarials
- 5.2.1.8** Anti-tuberculars/ Anti-TB

5.2.1.9 Anti-ulcerants

5.2.1.10 Anti-cancer

5.2.1.11 Anticonvulsants

5.2.1.12 Miscellaneous (multivitamins, multi minerals, cough syrups)

Above list covers a wide cross section of the drugs which are generally perceived to be most commonly counterfeited categories.

5.2.2 The detailed list of drugs studied under each therapeutic category is shown in Table 12.

5.2.3 Reputed top selling brand/generic was used to identify the brands for sampling. SEARPharm Forum's data based on press reports regarding spurious drugs was used to supplement the information for finalizing the list of medicines. The list of candidate drugs was finally short listed in consultation with prominent practicing community pharmacists.

### 5.3 PRICE RANGE

5.3.1 Each therapeutic category was stratified, based on the sale price of various drugs per sample in that category. Following price categorisations have been used for the study is shown in Table 4 below:

**Table 4:** Price range categories of samples

S.No.	Cost Range (INR)	Cost Range (US\$)
1	< 20	< 0.5
2	20 - 50	0.5 - 1.25
3	51 - 100	1.25 - 2.5
4	101 - 500	2.5 - 12.5
5	> 501	> 12.5

**5.4 SAMPLE SIZE** The minimum sample size for statistically significant results was determined to be 7,540. An attempt was made to collect two units of each of sample from each identified therapeutic categories from each Lol.

## 5.5 SAMPLING RATIO

**5.5.1** The areas (Lol) have been divided into two major categories

**5.5.1.1** Metros/Major cities

**5.5.1.2** District head quarters

**5.5.2** Samples have been drawn in the approximate proportion of 30:70 from metro/major cities and district head quarters.

## 5.6 STANDARD OPERATING PROCEDURES (SOP)

**5.6.1** The following SOPs were drawn up before the study initiation:

**5.6.2** List of SOPs

**5.6.2.1** Identification and deployment of Professional Associates

**5.6.2.2** Developing the Codes for samples, areas & Professional Associates

5.6.2.3 Confidentiality Agreement

5.6.2.4 Sample collection in the field

5.6.2.5 Packaging of samples collected for dispatch to the project office

5.6.2.6 Documentation of dispatch and records maintenance at site

5.6.2.7 Receipt of samples at the project office

5.6.2.8 Storage of samples

5.6.2.9 Inspection and Testing of samples

5.6.2.10 Report of samples

5.6.2.11 Payments to Professional Associates / Testing Laboratories

5.6.3 The SOP included the following information:

5.6.3.1 Isolation of the suspect samples

5.6.3.2 size of the samples required for testing purposes

5.6.3.4 manner in which the samples would be taken

5.6.3.5 record-keeping procedure to be followed in recording the details of action taken

## 6. OPERATIONAL PLAN

**6.1** For collection of samples, Professional Associates (PAs) were trained as 'mystery customers' to purchase medicines against prescriptions for testing purposes. The concept of mystery customers is routinely used in retail audit for gauging the service levels on scientific basis. The concept of 'surrogate patients/consumers' is used in similar manner in scientific studies. The Physician ensured that fifty-six medicines on the prescriptions covered all therapeutic areas and grouped them for different ailments. PAs visited the identified LOIs posing as mystery customers and purchased the medicines as per the sampling plans allocated. A conscious attempt was made that at least one sample of each category of drug was taken from a retail outlet near a government hospital in each Lol, and remaining samples were taken from retail outlets near railway stations/bus stands or market places. The PAs requested cash memos for purchased medicines but did not insist for it, since some retailers are known to be hesitant to issue cash memos. If a particular retail outlet did not have the required brand in stock, the PAs were expected to ask for a fast-moving substitute in that local area. Procurement of samples was documented in a 'Reporting Form' as per the SOPs, with details of date, place, name and address of the retail pharmacy, product details (brand name, manufacturer address, batch number, mfg. and expiry dates), number of samples purchased. Any unusual observations/comments/ queries were also recorded.

**6.2** The PAs collected medicines from the retail pharmacy outlets, packed the samples in zip-lock bags and personally transported them in large suitcases to the Project Office. In transit, suitcases were protected from light, humidity and high-temperatures. On return, PAs transferred the samples to a central location at the Project Office and kept them under ambient condition in corrugated boxes.

**6.3** The samples were double blinded through a coding system before they were taken-up for visual inspection and analysis, and the master coding list was kept confidential.

#### **6.4 CODING OF SAMPLES**

**6.4.1** The samples were coded to retain identity. The Reporting Forms were used to code the collected samples. Each code was unique to one particular type of sample. The code for the samples consisted of following parameters in sequential order;

**6.4.1.1** Dosage form of the sample / Initial of the PA+Zip lock Bag number assigned by the PA / Serial number of the brand

**6.4.2 Illustrations:** If a person called John collected Crocin tablets and kept it in bag number 005, with the serial number given to Crocin be 10, then as per the coding procedure:

**6.4.2.1** dosage form of the sample was ' T ' for tablet

**6.4.2.2** initial of the PA was ' J ' for John

**6.4.2.3** bag number given by the PA was ' 005 '

**6.4.2.4** serial number of the brand collected was ' 10 '

- Hence the code for this particular sample became T/ J005/ 10.
- If a substitute was collected then it was denoted by a prefix ' S '. Thus a substitute of Crocin was coded as T/ J005/ 10S. If samples were of different batch numbers then they were coded as a, b, c etc.
- Thus, if two different batches of Crocin have been collected from the same store, then they were coded as: T/J005/10a, T/J005/10b, T/J005/10c etc.
- A master list of coding was maintained in the project office.

## 6.5 VISUAL INSPECTION AND DOCUMENTATION

6.5.1 Training on visual inspection of different formulations viz. tablets, capsules, injectables, ointments/creams, syrups was imparted to PAs by a Quality Control expert. During visual inspection, for each type of formulation, the parameters to check were finalized, based on which the SOPs were developed. Different dosage forms and their corresponding parameters for visual inspection were identified and used. All samples of same brand from all the locations were displayed simultaneously for visual inspection. Each sample was inspected for abnormalities on packaging materials viz. colour, text, calligraphy on outer carton/aluminium foil strip/label, and for appearance, texture, clarity, uniformity, presence of foreign matter etc. of the formulations as shown in Table 5.

**Table 5:** Guidelines for physical inspection of formulations

Tablets	Capsules	Syrups	Ointments / creams /gels	Injection
<ul style="list-style-type: none"> <li>• Outer strip or blister</li> <li>• Calligraphy</li> <li>• Batch Coding</li> <li>• Printing quality</li> <li>• Tablet surface</li> <li>• Capping</li> <li>• Sticking/picking</li> <li>• Double impression</li> <li>• Black particles</li> <li>• Edges</li> <li>• Embossing</li> </ul>	<ul style="list-style-type: none"> <li>• Outer strip or blister</li> <li>• Calligraphy</li> <li>• Batch Coding</li> <li>• Printing quality</li> <li>• Powder outside</li> <li>• Denting</li> <li>• Brittleness</li> <li>• Foreign particles</li> <li>• Uniformity of powder</li> </ul>	<ul style="list-style-type: none"> <li>• Cap printing</li> <li>• Cap colour variation</li> <li>• Cap pealing of paint</li> <li>• Threading quality</li> <li>• Bottle surface</li> <li>• Bottle quality</li> <li>• Air bubble/crystals</li> <li>• Bottle size</li> <li>• Volume filled</li> <li>• Uniformity of solution</li> <li>• Particle size</li> </ul>	<ul style="list-style-type: none"> <li>• Tube quality</li> <li>• Caligraphy</li> <li>• Printing quality</li> <li>• Denting</li> <li>• Type of crimp</li> <li>• Information on crimp</li> <li>• Uniformity of cream</li> <li>• Separation of phases</li> <li>• Presence of grittiness</li> <li>• Quality of laquering</li> </ul>	<ul style="list-style-type: none"> <li>• Printing/ caligraphy</li> <li>• Embossing of seal</li> <li>• Foreign particles</li> <li>• Colour of solution</li> <li>• Clarity of solution</li> <li>• Volume of contents</li> <li>• Uniformity of solution</li> <li>• Quality of ampoule sealing</li> </ul>

**6.6** Visually suspected units were identified, photographed and were sent in duplicate for assay to one of the three NABL (National Accreditation Board for Testing and Calibration Laboratories) approved laboratories located in different Office as a reference sample.

**6.6.1** After inspection, all suspects plus arbitrarily selected remaining samples from non-suspects covering all the regions, so as to make-up 20% of the total samples were sent to one of the three selected NABL approved laboratories for assay.

**6.6.2** All the three selected NABL approved laboratories were provided with same brief on the conduct of analysis as per Pharmacopoeial status mentioned on label. All visual inspection reports of PAs were confidentially handed over to a quality expert for decision on sending the suspected samples for chemical analysis.

**6.7** After getting the certificate of analysis from the laboratories, the data was collated, codified, cleaned and was entered into a special package developed for it. The results were subjected to statistical data analysis. Then the data was extrapolated over each particular product's total sale across respective territory as well as across the entire country. For obtaining a larger picture, the data was pooled and extrapolated over country's overall value of pharmaceutical products and documented with evidence.

**6.8** A final report projecting possibility regarding the extent of spurious (suspected counterfeits) medicines in India, most and least affected therapeutic medicine segments, most and least affected regions, states, and cities in the country was documented.

**6.6.5** The findings of the study were presented to WHO-SEARO and their comments were incorporated in the report.

**6.6.6** As suggested by the WHO-SEARO, a request will be sent to the concerned manufacturers whose products were identified as suspected counterfeits to provide two 'reference samples' of each product for comparison. In case some manufacturers do not provide reference samples, the same will be procured from their authorized dealers. The number of samples received directly from manufacturers or through authorized dealers will be mentioned in the subsequent updates.

**6.6.7** Thereafter, the findings will be shared with concerned manufacturers whose products were identified as suspected counterfeits for their information and confirmation whether they were counterfeits or genuine.

## 7. RESULTS

### 7.1 ANECDOTAL EXPERIENCES

7.1.1 The Professional Associates (PAs) contacted 234 chemist shops throughout the country for samples

7.1.1.1 General reaction of chemists or persons behind the counter was an element of surprise and enquiry why therapeutic prescriptions of different conditions were presented and basket of medicines purchased. In such situations, it was not uncommon for the chemist to make phone calls (may be either to owner or to a pharmacist in another shop) to confirm if medicines should be dispensed. Such consultations often resulted in the suspicion that the PAs may be from Drugs Regulatory agency or NGO or students interested in a project to study quality of medicines. The transaction led to questioning related to identity of the PAs, physician who prescribed, the patient details, why all the prescriptions were generated at same address, why so many prescriptions/medicines at a time etc. Some chemists even looked for bags which the PAs were carrying. Some chemists were curious if medicines were for a dispensing doctor or for re-sale in village shops. After interrogation, ten chemists (4.3%) refused dispensing of medicines due to suspicion.

7.1.1.2 When dispensing substitutes, some chemists soon realized and replaced immediately products from local brands with those prescribed. When PAs asked why they are replacing, answer was "*these medicines are not of your type*".

7.1.1.3 PAs expected to receive but did not insist on invoice, and therefore, some transactions without cash memo/cash memo without batch details were even accepted. Some chemists refused to give cash memo.

7.1.1.4 While refusing a cash memo, a chemist made an excuse that as per the Drugs and Cosmetics Act, cough syrups could not be dispensed with prescriptions bearing old date.

**7.1.1.5** In one instance, when the PAs asked for two units of a brand of Methylprednisolone sodium 500mg injection, he arranged one unit from another chemist. Later, when PAs went to near by pharmacy, the chemist immediately contacted the previous chemist and enquired if the same person came to him to purchase same medicine. Subsequently, both chemists gathered and interrogated the PAs on why they were purchasing from different chemists.

**7.1.1.6** A chemist at Bhagirath Palace, New Delhi enquired if PAs were interested in purchasing local brands of Sildenafil Citrate tablets which were in great demand.

## 7.2 CATEGORY-WISE DISTRIBUTION OF SAMPLES

**7.2.1** A total of 10,743 samples of 56 brands/generics were collected from 15 states covering 38 Lols in 5 regions throughout the country and inspected. The samples were collected in duplicate, for example, 10,000 samples in duplicate (viz.  $5000 \times 2 = 10000$  samples). The tables 5 and 6 show distribution of samples a) region-wise, b) regulatory enforcement category-wise c) cost range-wise and therapeutic category-wise respectively.

**Table 6:** Distribution of samples under Region and Regulatory category

Region	Regulatory category of states			Total
	Strong	Medium	Weak	
North	790	0	3238	4028
South	431	1758	0	2189
East	0	1330	1079	2409
West	1049	0	0	1049
Central	0	0	1068	1068
Total	2270	3088	5385	10743

Table 7: Distribution of samples under Cost range and Therapeutic Categories

Cost-range	Therapeutic Categories of drugs											Total	
	Anti-infectives	Steroids	Anti-histamines	CVDs	Anti-diabetics	NSAIDs	Anti-malarials	Anti-TB	Miscellaneous	Anti-ulcerants	Anti-cancer		
< 20	431	386	472	332	391	940	250	0	367	395	181	158	4303
20 - 50	1243	193	0	297	296	663	2	135	211	394	0	0	3434
51 -100	391	2	0	324	213	309	227	0	111	621	0	0	2198
101 - 500	239	0	0	0	0	0	2	209	119	0	0	0	569
> 501	0	50	0	0	0	0	0	189	0	0	0	0	239
Total	2304	631	472	953	900	1912	481	533	808	1410	181	158	10743

### 7.3 VISUAL INSPECTION OF SAMPLES

**7.3.1** The visual inspection provides a first inference of any unusual sign in product presentation. Some striking differences from the visual inspection of 10,743 samples provided a list of suspects. The following tables 7, 8 and 9 show distribution of counterfeit suspects identified after visual inspection under region-wise, regulatory category-wise, cost range-wise respectively.

**Table 8:** Distribution of counterfeit suspects after physical inspection under each Region in the country

Region	Count and per cent in the region	Status of Visual inspection of samples: N=suspect, Y= Ok		Total
		N	Y	
North	Count	121	3907	4028
	% within Region	3.0%	97.0%	100.0%
South	Count	50	2139	2189
	% within Region	2.3%	97.7%	100.0%
East	Count	77	2332	2409
	% within Region	3.2%	96.8%	100.0%
West	Count	42	1007	1049
	% within Region	4.0%	96.0%	100.0%
Central	Count	45	1023	1068
	% within Region	4.2%	95.8%	100.0%
Total	Count	335	10408	10743
	% within Region	3.1%	96.9%	100.0%

**Table 9:** Distribution of counterfeit suspects after physical inspection under each Regulatory category

Regulatory category	Count and per cent in regulatory category of states	Status of Visual inspection of samples: N=Suspect, Y= Ok		Total
		N	Y	
Strong	Count	74	2196	2270
	% within Regulation of States	3.3%	96.7%	100.0%
Medium	Count	70	3018	3088
	% within Regulation of States	2.3%	97.7%	100.0%
Weak	Count	191	5194	5385
	% within Regulation of States	3.5%	96.5%	100.0%
Total	Count	335	10408	10743
	% within Regulation of States	3.1%	96.9%	100.0%

**Table 10:** Distribution of counterfeit suspects after physical inspection under each Cost range

Cost range (INR)	Count and per cent in cost range	Status of Visual inspection of samples: N=Suspect, Y= Ok		Total
		N	Y	
less than 20	Count	225	4078	4303
	% within Cost range	5.2%	94.8%	100.0%
20 - 50	Count	75	3359	3434
	% within Cost range	2.2%	97.8%	100.0%
51 -100	Count	31	2167	2198
	% within Cost range	1.4%	98.6%	100.0%
101 - 500	Count	0	569	569
	% within Cost range	.0%	100.0%	100.0%
More than 500	Count	4	235	239
	% within Cost range	1.7%	98.3%	100.0%
Total	Count	335	10408	10743
	% within Cost range	3.1%	96.9%	100.0%

**Table 11:** Distribution of counterfeit suspected samples after physical inspection under each Therapeutic Category

Therapeutic Categories of drugs	Count and per cent in cost range	Status of visual inspection of samples: N=Suspect, Y=Ok		Total
		N	Y	
Anti-infectives	Count	80	2224	2304
	% within Therapeutic Category of drugs	3.5%	96.5%	100.0%
Steroids	Count	41	590	631
	% within Therapeutic Category of drugs	6.5%	93.5%	100.0%
Anti-histamines	Count	55	417	472
	% within Therapeutic Category of drugs	11.7%	88.3%	100.0%
Cardio Vascular	Count	6	947	953
	% within Therapeutic Category of drugs	0.6%	99.4%	100.0%
Anti-diabetics	Count	8	892	900
	% within Therapeutic Category of drugs	0.9%	99.1%	100.0%
NSAIDs	Count	79	1833	1912
	% within Therapeutic Category of drugs	4.1%	95.9%	100.0%
Anti-malarials	Count	22	459	481
	% within Therapeutic Categories of drugs	4.6%	95.4%	100.0%
Anti-TB	Count	0	533	533
	% within Therapeutic Category of drugs	0.0%	100.0%	100.0%
Miscellaneous	Count	12	796	808
	% within Therapeutic Category of drugs	1.5%	98.5%	100.0%

Therapeutic Categories of drugs	Count and per cent in cost range	Status of visual inspection of samples: N=Suspect, Y=Ok		Total
		N	Y	
Anti-ulcerants	Count	14	1396	1410
	% within Therapeutic Categories of drugs	1.0%	99.0%	100.0%
Anti-cancer	Count	18	163	181
	% within Therapeutic Categories of drugs	9.9%	90.1%	100.0%
Anti-convulsant	Count	0	158	158
	% within Therapeutic Categories of drugs	.0%	100.0%	100.0%
Total	Count	335	10408	10743
	% within Therapeutic Categories of drugs	3.1%	96.9%	100.0%

### 7.3.1 Product-wise findings

**Table 12:** Product-wise list of samples, suspects, reasons for suspicion, samples analysed and failed

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
1	Cefotaxime sodium 125mg injection	237	0	• None	21	None
2	Gentamycin sulphate injections	195	8	• Vials with and without flip-off seals • Brand and generic with no price difference	20	2

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
3	Pheniramine maleate 25mg tablets	314	24	<ul style="list-style-type: none"> <li>• Printed and plain foil with shade differences</li> <li>• Company logo in different fonts</li> </ul>	21	None
4	Cetirizine 10mg tablets	152	12	<ul style="list-style-type: none"> <li>• Strips in different colour and illegible Batch details</li> </ul>	11	None
5	Betamethasone sodium phosphate 0.1% & Neomycin Sulphate 0.5% Eye/ear drops	204	26	<ul style="list-style-type: none"> <li>• Outer carton with different colour shades</li> </ul>	18	None
6	Dexamethasone sod. phosphate 4mg/ml injection	182	6	<ul style="list-style-type: none"> <li>• Printing on blister strip with shade variance</li> </ul>	17	None
7	Ibuprofen 400mg & Paracetamol 325mg tablets	360	34	<ul style="list-style-type: none"> <li>• Tablets in varying white shades</li> <li>• Shade differences in printed strip foil</li> <li>• Plain rear foil with different sheen</li> <li>• Company logo in different font sizes</li> </ul>	29	None

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

<b>Product Code</b>	<b>Product Name</b>	<b># of Samples</b>	<b># of Suspects</b>	<b>Remarks</b>	<b># of Samples sent for Assay</b>	<b># Failed</b>
8	Diclofenac Sodium 50mg tablets	235	6	<ul style="list-style-type: none"> <li>• Tablets in varying shades of enteric coating</li> <li>• Difference in strip text colour</li> </ul>	16	None
9	Paracetamol 500mg tablets	345	24	<ul style="list-style-type: none"> <li>• Illegible printing of batch details</li> <li>• Strip foil text with colour shade differences</li> <li>• Strips with round and capsular shape tablets</li> </ul>	24	None
10	Atenolol 25mg tablets	334	6	<ul style="list-style-type: none"> <li>• Different font size of brand name, font spacing and colour shade of strip text</li> </ul>	25	None
11	Glipizide BP 5mg tablets	198	2	<ul style="list-style-type: none"> <li>• Two types of batch numbering and printing codes</li> <li>• Rear-foil: With and without brand name</li> </ul>	21	None

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
12	Metformin HCl 500mg tablets	193	6	<ul style="list-style-type: none"> <li>• Tablets with rough surface, broken edges and differences in bisect</li> <li>• Size of text (brand name) and colour shade</li> <li>• Strips foil with different design, layout and sizes</li> </ul>	22	None
13 (A)	Amikacin Sulphate 100mg injection (Brand A)	181	14	<ul style="list-style-type: none"> <li>• Label composition expressed per vial and per ml</li> <li>• Brand highlighted in dark blue and green rectangular boxes</li> <li>• Boxed warning in black and red text</li> <li>• Company logo in dark blue and red colours</li> <li>• Storage condition in UPPER and Sentence Case</li> </ul>	17	None
13 (B)	Amikacin Sulphate 100mg injection (Brand B)			<ul style="list-style-type: none"> <li>• Vials found in aluminum-foil and paper-poly packs</li> </ul>		

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
13 (C)	Amikacin Sulphate 100mg injection (Brand C)			<ul style="list-style-type: none"> <li>• Labels of vials and cartons in different designs</li> <li>• Company name in different sizes and in orange and blue colour in different places</li> <li>• Presence and absence of pictograms</li> </ul>		
14	B-complex with Vitamin C	370	0	<ul style="list-style-type: none"> <li>• No remarks</li> </ul>	27	None
15	Carbamazepine 200mg	158	0	<ul style="list-style-type: none"> <li>• No remarks</li> </ul>	15	None
16	Ranitidine 150mg tablets	395	4	<ul style="list-style-type: none"> <li>• Tablets with different thickness</li> <li>• Strip foil in different sizes</li> </ul>	24	None
17	Chloroquine 250mg tablets	252	4	<ul style="list-style-type: none"> <li>• Strip foils text in different colour shades, font types and font sizes</li> </ul>	23	None
18	Ciprofloxacin HCl 250mg tablets	173	2	<ul style="list-style-type: none"> <li>• Strips with and without holograms</li> <li>• Strips foil with different design, layout and sizes</li> </ul>	16	None
19	Cefadroxil HCl 250mg tablets	148	16	<ul style="list-style-type: none"> <li>• Differences in foil strip text colour, length and font sizes</li> <li>• Worn and tattered strips</li> </ul>	14	None

EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
20 (A)	Ampicillin 250 mg & Cloxacillin 250 mg capsules (Brand A)	132	8	• Capsule with and without company and brand names	11	None
20 (B)	Ampicillin 250 mg & Cloxacillin 250 mg capsules (Brand B)			• Aluminum strip and blister packs		
21	Rifampicin 300mg capsules	135	0	• None	13	None
22	Povidone Iodine 0.5% W/W ointment	160	0	• None	13	None
23	Erythromycin Estolate 250 mg tablets	137	2	• None	13	None
24	Amoxicillin 250mg capsules	149	0	• None	11	None
25	Codein phosphate 4mg & CPM 10mg Syrup (Brand A)	89	0	• None	14	None
26	Beclomethasone dipropionate 0.025%, Clotrimazole 1%, & Neomycin sulphate 0.5% cream	344	22	• Tubes with and without manufacturer's name/code on the crimp	29	None

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
27	Nimesulide 100mg tablets	661	0	• None	48	None
28	Diltiazam HCl 30mg tablets	105	0	• None	12	None
29	Atenelol 25mg tablets	98	0	• None	10	None
30	Ramipril 2.5mg tablets (Brand A)	90	4	• Product in capsule and tablet dosage forms	9	None
31	Glimepiride 1mg tablets (Brand A)	298	0	• None	29	None
32 (A)	Pantoprazole 40mg tablets (Brand A)	135	8	• Foil strip in different font style and size • Company logo and Rx legend in different sizes	11	None
32 (B)	Pantoprazole 40mg tablets (Brand B)			• Difference in strip text size • Different types of batch numbering		
32 (C)	Pantoprazole 40mg tablets (Brand C)			• Company logo in different colours, sizes and formats		
33	Belcomethasone Dipropionate 0.025% / Clotrimazole 1% / Neomycin Sulphate 0.5% cream	85	0	• None	9	None

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
34	Omeprazole 20mg capsules (Brand A)	259	2	<ul style="list-style-type: none"> <li>• Foils in different colour shades</li> </ul>	16	None
35	Elemental Calcium 500mg and Cholecalciferol (vitamin D3) 250 IU	131	12	<ul style="list-style-type: none"> <li>• Different types of batch numbering</li> </ul>	12	None
36	Betamethasone 0.01% w/w & Clioquinol 3%w/w cream	110	0	<ul style="list-style-type: none"> <li>• No remarks</li> </ul>	9	None
37	Cefuroxime axitil 250 tablets	143	0	<ul style="list-style-type: none"> <li>• No remarks</li> </ul>	13	None
38	Cephalexin 250mg capsules	127	10	<ul style="list-style-type: none"> <li>• Foils in different colour shades</li> <li>• Leakage of powder and broken capsules</li> </ul>	10	None
39	Roxithromycin 150 mg tablets (Brand A)	121	6	<ul style="list-style-type: none"> <li>• Strip printing in dark and light blue shades</li> <li>• Batch numbering with different font types</li> <li>• Presence and absence of hologram</li> <li>• Rear foil shows company logo in different calligraphies</li> </ul>	13	4

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
40	Ramipril 2.5mg tablets (Brand B)	326	0	• No remarks	30	None
41	Glimepiride 1mg tablets (Brand B)	211	0	• No remarks	21	None
42	Omeprazole 20mg capsules (Brand B)	232	0	• No remarks	16	None
43	Lansoprazole 30mg capsules	178	0	• No remarks	17	None
44	Pantoprazole 40mg tablets (Brand D)	211	0	• No remarks	15	None
45	CPM 10mg & Codein phosphate 4mg syrup (Brand B)	102	0	• No remarks	15	None
46	Diclofenac sodium & linseed oil gel	311	0	• No remarks	29	None
47	Artesunate 50mg tablets	229	6	• Difference in design & strip layout, text colour	17	None
48	Cefuroxime axetil 250mg tablets	43	0	• No remarks	3	None
49	Amoxicillin 250 mg & Clavulanic acid 125 mg tablets	100	0	• No remarks	10	2

**EXTENT OF SPURIOUS (COUNTERFEIT) MEDICINES IN INDIA**

Product Code	Product Name	# of Samples	# of Suspects	Remarks	# of Samples sent for Assay	# Failed
50	Ceftazidime injection	75	0	• No remarks	7	None
51	Roxithromycin 150mg tablets (Brand B)	21	0	• No remarks	1	None
52	Ethambutol 800mg, INH 300mg tabs. & Rifampicin 450mg caps: Kit of tablets & capsules	209	0	• No remarks	10	None
53	Calcium Gluconate 10%w/v injection	71	0	• No remarks	7	None
54	Trypsin 85714.28 units & Chymotrypsin 14285.72 units tablets	48	0	• No remarks	6	None
55	Ethambutol 800mg/ INH 300mg & Pyrazinamide 750mg & Rifampicin 450mg: Kit of tablets & capsules	189	0	• No remarks	11	None
56	Methyl-prednisolone sodium 500mg injection	50	0	• No remarks	5	None

## 7.4 LABORATORY ANALYSIS OF SAMPLES

As per the study design protocol, the samples after the visual inspection and physical verification were sent to NABL approved analytical laboratories for estimation of the drug content as per the label claim. The results obtained are tabulated and interpreted.

**Table 13:** Distribution of samples sent to NABL laboratory for testing

Description	Number of samples	Per cent	Cumulative Per cent
Not sent for test	8288	77.1	77.1
Sent for lab test	2455	22.9	100.0
Total	10743	100.0	

**Table 14:** Results of the NABL report of samples sent for analysis

Description	Result of NABL report		Total
	Fail	Pass	
Count	8	2447	2455
Per cent	0.3%	99.7%	100.0%

**Table 15:** Distribution of failing samples under different regions in the country

Region	Count and per cent in region	Result of NABL report		Total
		Fail	Pass	
North	Count	0	713	713
	Per cent	0%	100.0%	100.0%
South	Count	0	451	451
	Per cent	0%	100.0%	100.0%
East	Count	4	755	759
	Per cent	0.5%	99.5%	100.0%
West	Count	2	263	265
	Per cent	0.8%	99.2%	100.0%
Central	Count	2	265	267
	Per cent	0.7%	99.3%	100.0%
Total	Count	8	2447	2455
	Per cent	0.3%	99.7%	100.0%

**Table 16:** Distribution of failing samples under different regulatory category of states

Regulatory Category of states	Count and per cent in regulatory category	Result of NABL report		Total
		Fail	Pass	
Strong	Count	2	472	474
	% within Regulation of States	0.4%	99.6%	100.0%
Medium	Count	0	797	797
	% within Regulation of States	0.0%	100.0%	100.0%
Weak	Count	6	1178	1184
	% within Regulation of States	0.5%	99.5%	100.0%
Total	Count	8	2447	2455
	% within Regulation of States	0.3%	99.7%	100.0%

Table 17: Distribution of failing samples under different Cost range

Cost range (INR)	Count and per cent in cost range	Result of NABL report		Total
		Fail	Pass	
less than 20	Count	2	906	908
	% within Cost range	0.2%	99.8%	100.0%
20 - 50	Count	0	798	798
	% within Cost range	0%	100.0%	100.0%
51 -100	Count	4	483	487
	% within Cost range	0.8%	99.2%	100.0%
101 - 500	Count	2	204	206
	% within Cost range	1.0%	99.0%	100.0%
More than 500	Count	0	56	56
	% within Cost range	0%	100.0%	100.0%
Total	Count	8	2447	2455
	% within Cost range	0.3%	99.7%	100.0%

Table 18: Distribution of failing samples under different Therapeutic categories

Therapeutic Category	Count and per cent in cost range	Result of NABL report		Total
		Fail	Pass	
Anti infective	Count	8	469	477
	% within Therapeutic Category	1.7%	98.3%	100.0%
Steroids	Count	0	130	130
	% within Therapeutic Category	0%	100.0%	100.0%
Anti-histamine	Count	0	87	87
	% within Therapeutic Category	0%	100.0%	100.0%
CVDs	Count	0	219	219
	% within Therapeutic Category	0%	100.0%	100.0%
Anti diabetic	Count	0	257	257
	% within Therapeutic Category	0%	100.0%	100.0%
NSAIDs	Count	0	454	454
	% within Therapeutic Category	0%	100.0%	100.0%
Anti-malarials	Count	0	119	119
	% within Therapeutic Category	0%	100.0%	100.0%
Anti TB	Count	0	215	215
	% within Therapeutic Category	0%	100.0%	100.0%
Miscellaneous	Count	0	173	173
	% within Therapeutic Category	0%	100.0%	100.0%
Anti-ulcerants	Count	0	245	245
	% within Therapeutic Category	0%	100.0%	100.0%
Anti-cancer	Count	0	42	42
	% within Therapeutic Category	0%	100.0%	100.0%
Anticonvulsant	Count	0	37	37
	% within Therapeutic Category	0%	100.0%	100.0%
Total	Count	8	2447	2455
	% within Therapeutic Category	0.3%	99.7%	100.0%

## 8. CONCLUSIONS

**8.1** During visual inspection, the extent of counterfeit suspects were to the tune of 3.1 per cent. These were assumed due to striking registration differences in the packaging of same product viz. company logo, brand name and manufacturer's name; printing of batch details; colour shades; layout and sizes text matters; expression of composition; highlighting brand name and warnings; calligraphy of storage text; sizes of Rx legends; presence/absence of holograms; coding on tubes; and presence/absence flip-off seals on vials. At the same time, in formulations, the major differences were found in colour shade/size, bisect and integrity of tablets; presence/absence of circular printing of brand name and company logo in capsules; capsule/tablet dosage forms in same strength; leakage of powder and broken capsules.

**8.1.1** Based on the domestic sales of INR 31,500 crore (7 billion USD) in 2006, the extent of suspected counterfeit medicines would be extrapolated to approximately to INR 1000 crore (USD 250 million). These figures are considerably lower than INR 4000 crore (USD 1000 million) in earlier reports.

**8.1.2** The extent of relative prevalence of counterfeit suspects in different categories of states perceived to be strongly, medium or weakly regulated was to the tune of 3.3%, 2.3% and 3.5% respectively. It is evident that even from the states perceived to be strongly regulated, the percentage of counterfeit suspects is almost same as weakly regulated.

**8.1.3** In terms of cost ranges, the extent of relative prevalence of counterfeit suspects were in INR <20 is 5.2%; INR 20-50 is 2.2%; INR 51-100 is 1.4%; INR 101-500 is nil and INR >500 is 1.7%. These findings show that medicines in price range of less than INR 20 per sample are maximum targets for counterfeiting. This is contrary to the belief that the high cost medicines are more prone to counterfeiting.

**8.1.4** In terms of therapeutic categories studied, the extent of relative prevalence of counterfeit suspects were: Anti-infectives 3.5%; Steroids 6.5%; Anti-histamines 11.7%; CVDs 0.6%; Anti-diabetics 0.9%; NSAIDs 4.1%; Anti-malarials 4.6%; Anti-TB Nil; Anti-ulcerants 1%; Anti-cancer 9.9%; Anticonvulsant nil and Miscellaneous 1.5%. While the medicines in anti-histamine category were found to be more prone to counterfeiting, at the same time, it is noteworthy to mention that among anti-TB and anticonvulsant drugs no samples of counterfeit suspects were detected.

**8.1.5** The extent of relative prevalence of counterfeit suspects in various regions of India was North 3%; East 3.2%; South 2.8%; Central 4.21% and West 4%. This shows that the high and low prevalence of counterfeit suspects was in Central and southern regions in the country respectively.

**8.1.6** The state-wise data revealed the following extent of relative prevalence of counterfeit suspects: Andhra Pradesh 1.25%; Assam 0.3%; Bihar 5.65%; Chattisgarh 3.05%; Goa 1.05%; Gujarat 4.6%; Haryana 2.65%; Karnataka 3.1%; Madhya Pradesh 1.5%; Maharashtra 4.15%; NCT Delhi 1.2%; Orissa nil; Punjab 0.9%; Rajasthan 4.35%; Tamil Nadu 2.05%; Uttar Pradesh 0.75% and West Bengal 4.55%. The data shows that Bihar has highest probability of counterfeit suspects amongst various states under study.

**8.2** Of the total samples, 22.9 per cent of all suspects plus arbitrarily selected non-suspects were sent to NABL approved laboratories for analysis. While predominantly the assay results from all twelve therapeutic categories lay within the Pharmacopoeial standards/label claim with the following exceptions:

**8.2.1** Four samples of anti-infective brand containing Roxithromycin BP 150mg tablets failed to meet the pharmacopoeial standard of assay. Two failing samples showed 6.62% and the other two samples were 11.92% of label claim. The same samples were also identified as counterfeit suspects during visual

inspection for discrepancy in company logo on rear foil, calligraphy, batch number and hologram.

**8.2.2** Two samples of another anti-infective brand containing Gentamycin sulphate 20mg per 2ml injection were not within pharmacopoeial limit of assay. As per the pharmacopoeia or label claim, Gentamycin sulphate 20mg should meet the range between 19 - 22mg per 2 ml, however, these samples showed only 18.33mg per 2 ml. The market samples had vials with and without flip-off seals.

**8.2.3** Two samples of another anti-infective brand containing Amoxicillin 250mg and Clavulanic acid 125mg tablets were not within pharmacopoeial limit of assay. These samples showed only 92.72mg (37.09%) of Amoxicillin and 5.40mg (4.32%) of Clavulanic acid of label claim.

**8.2.4** Overall, the certificates of analysis showed 8 samples (0.3 per cent) did not meet the pharmacopoeial standard/label claim. The failing samples were all from the anti-infective category, further substantiating the results of the earlier international study published in Lancet that anti-infectives were more prone to counterfeiting.

**8.3** It may be reemphasized that during visual inspection, the extent of counterfeit suspects were to the tune of 3.1 per cent. However, from the laboratory analysis, 0.3 per cent did not meet the pharmacopoeial standards in terms of label claim. As stated earlier, counterfeit drugs may comply with quality standards while imitating popular brands.

## 9. LESSONS LEARNT AND NEXT STEPS

**9.1** Each PA presenting set of prescriptions with different therapeutic categories to a chemist lead to suspicion resulting in ten chemists (4.3%) refusing to dispense medicines. The research methodology in sample collection therefore requires little modification.

**9.2** Due to limited samples and budget constraints, only assays were conducted. For future studies, it is important to conduct all prescribed pharmacopoeial tests. This will give more comprehensive picture on the extent of counterfeit medicines.

**9.3** While the study addressed the extent of spurious drug prevalence in India; relative prevalence of spurious drugs in various states and regions; estimation of approximate volume and percentage of spurious drugs available through retail drug stores; prevalence of spurious drugs in various identified therapeutic segments and estimation of the extent of spurious drugs in the identified segments, it was not meant to address the following issues:

**9.3.1** Extent of spurious drugs exported from India

**9.3.2** Extent of spurious drugs circulating in inter-country commerce

**9.3.3** Extent of spurious drugs prevailing in other than retail sale channels

**9.3.4** Extent of spurious drugs prevailing in small towns and rural areas

**9.3.5** Extent of spurious drugs of brands of relatively smaller manufacturers

**9.3.6** Extent of spurious drugs of relatively low sales turnover products

Above categories must be covered in a separate study, to obtain a more comprehensive picture of the situation.

**9.4** The model as such can be applied to study the extent of counterfeit medicines or in individual therapeutic category of medicines. Potential categories are Anti-infectives, Anti-TB, Anti-malarials and ARV drugs.

**9.5** Another application of the model is its usefulness by drug procurement agencies and chain pharmacies doing bulk purchases in detecting suspected counterfeits as a preventive tool.

## 10. REFERENCES

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