Proposed Methodology to conduct a study on the Extent of SPURIOUS DRUGS in the Supply Chain of Indian Market

By

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Building International Cooperation to Protect Patients

Background

In 2010, the total pharmaceutical market in India was over INR 55,000 crores. The retail sector accounted for 85%, the hospital sector accounted for 9% and the doctor segment accounted for 6%. Indian pharmaceutical market is highly fragmented with a strong presence of domestic companies, which together account for more than 70 percent of domestic sales. The Indian manufacturing sector comprises of large, medium and small scale manufacturers. (IMS health, 2010).

Present day complexities in the distribution systems lend themselves to several entry points for spurious 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, spurious 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 spurious drugs. (SEARPharm Forum, 2007).

As per data of the state drug controllers during the period 2003-2008, 6.3 to 7.5% of the samples tested were found to be of substandard quality and 0.16 to 0.35% were found to be spurious (CDSCO, 2009).

Counterfeiting is a criminal activity. It can be organised, unorganised or one off episodes and hence difficult to catch the culprits. At the same time it is a highly sophisticated operation. Manufacture and sale of spurious drugs is primarily a clandestine activity. To this extent, it is difficult to detect the manufacturer or movement of spurious drugs. Any effective action against this activity would require **continuous surveillance** by the regulators and active co-operation from the law and order Enforcement machinery and other stake holders in the States including patients.

Spurious and not of Standards medicines have raised a global outcry from patient's groups and consumers due to several media reports and lack of prompt regulatory intervention, which has created doubts and mistrust in the existing supply chain in the country. India is one of the leading countries in the world to manufacture and supply medicines globally to enable citizens to access quality medicines at the most affordable price.

The media reports on spurious drugs in the country do not provide a balanced picture and has, therefore, caused serious apprehension. It is always possible that the quoted facts, stories and statistics feed on each other has resulted in distorted and exaggerated projections, which further confuses the consumers.

On account of apprehensions about the availability of safe and genuine medicines in India, concerns are raised not only by the consumers within India but is also globally, which is affecting the credibility of drugs produced in India. Consumers procure their medicines primarily from retail market. In addition, other outlets are CGHS dispensaries, railway dispensaries, army and government hospitals, ESIS and dispensing doctors and direct imports.

In India, in the recent times, there have been two major studies. The first was by SEARPharm Forum (FIP/WHO Forum of National Pharmaceutical Associations of SEAR) and the Second by CDSCO (Central Drugs Standard Control Organisation). Both the studies attempted to estimate the extent of spurious medicines () circulating in Indian Market. Off late, need has been felt to carry out such a study that it captures what was not done earlier and innovative to estimate the extent of spurious medicines available at the user-end/patients.

Often doubts have been raised about safety to patients due to spurious medicines as the spurious medicines may or may not contain labelled drug with specified ingredient or contain different drug and hence patient may or may not get the desired therapeutic benefit. Therefore it is essential to focus the study on the scope and definitions of not-of-standard and spurious medicines and differentiate between spurious and not-of-standard medicines as per regulation. In addition to appearance and potency, also carry out further testing like disintegration time and dissolution rates as applicable as per pharmacopoeial specifications, which will suggest the probability of lack of bioavailability of the drug in body fluids bringing out safety issues.

The study should offer a practical and perpetual model for the collection of information and create feedback through consumer participation. Such an ongoing study should enable assessment of the drugs available in India for compliance with regulations pertaining to pharmaceopoeial standards and spurious drugs as defined in the regulation. The generated data can then be extrapolated to get a clearer understanding of the extent of the problem across the entire country.

The other aspect is designing a consumer based study, determining size of the sample, modalities of sample collection and testing, using NABL and approved laboratories. During several consultations held so far by PSM India Initiative, suggestions were brought out on how to involve urban, rural and remote areas, involving civil society organisations, Panchayat, end-users and Patient groups etc. This can further be facilitated by establishing state nodal contact points both for sample collection and testing. Such a study would also provide an opportunity to understand the consumer behaviour towards use of medicines.

The study should focus but not limited to on 348 essential drugs and/or medicines for serious ailments like TB, Malaria, HIV aids and Cancer, in conventional as well as controlled release, fixed dose combinations and vulnerable categories like anti-infectives, antidiabetics etc.. The intention should be to cover all therapeutic areas, branded and generics at different price levels.

It must be made clear that the study is not intended for prosecution and does not take into account Indian medicines circulating in international market.

Unsafe drugs could be

- **Spurious drugs,**
- **Not-of-Standard, sub therapeutic, unlicensed drugs**
- **Drugs manufactured under improper condition (non compliance of GMP)**
- **improperly stored drugs,**
- **Having unfavorable benefit risk profile**

The overall objective of a Drug Regulatory Authority (DRA) is to ensure that medicinal products are of acceptable quality and manufactured and distributed in ways, which ensure their quality until they reach the patient/consumer, and their commercial promotion is accurate.

Consumer have the right to expect that Drug Administration will not just protect the public health by keeping unsafe drug off the market but facilitate the availability of safe and effective drugs.

INDIAN SCENARIO

- The spurious medicines trade is believed to be 30 to 40 percent of total market as focused by the media; however, there is lack of scientific evidence.
- Data generated on the legal samples drawn by Drugs Inspectors throughout India shows the extent of spurious drugs vary between 0.3 to 0.4 %
- A survey funded by WHO & carried out by SEARPharm Forum, in collaboration with Delhi Pharmaceutical Trust with technical assistance with apothecaries foundation in 2007 for 10,743 samples from 56 brands procured from 234 retail outlets throughout the country, showed 3.1% spurious suspects during visual inspection and 0.3% did not meet the pharmacopoeial standards during laboratory analysis.
- Countrywide Survey for Spurious Drugs' was carried out by CDSCO in 2008-09 based on statistical methodology of determining the sample size advised by Indian Statistical Institute, Hyderabad. According to the report extent of spurious/counterfeit was in the tune of around 0.05 per cent (11 samples were not accepted by the respective manufacturers out of 24,136 collected samples).

Definition of Spurious Drugs:

> *Spurious Drugs are mainly the products which are deliberately and fraudulently mislabeled and manufactured to mislead and misrepresent the patients by concealing their identity, source of manufacture and its content to profiteer on the popularity of fast moving branded or generic medicines. It may or may not contain the active ingredients in the manner mentioned on the label.*

For the purpose of the study, the drug shall deem to be spurious if it falls within the definition as per Chapter IV, Sec. 17B of the D&C Act:

a) If it is manufactured under a name which belongs to another drug; or

b) If it is 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

c) If the label or container bears the name of an individual or company purporting to be manufacturer of the drug; which individual or company is fictitious or does not exist; or

d) If it has been substituted wholly or in part by another drug or substance; or

e) If it purports to be the product of a manufacturer of whom it is not truly a product.

Definition of standards to be complied:

For the purpose of the study, the drug shall deemed to be not-of-standard quality if it fails to comply with the standard as per Chapter V, The Second Schedule, sec 5(a), (b) of the Drugs & Cosmetic Act.

Collection of Drug Samples

Involvement of patient/consumer during sampling: It is proposed that consumers would be encouraged to donate samples they wish to get examined, in exchange the same medicine will be provided free of cost. As soon as the offer comes to the NCP over a toll free phone number or my email, after due diligence of the caller, the sealed genuine sample will get collected through an authorized courier from the donor's doorstep. The same samples will be handed over to NCP in a sealed manner duly signed along with a questionnaire. This message shall be communicated to the citizens through a multi-media campaign involving the Ministry of Consumer Affairs, Government of India under their on-going scheme JAGO GRAHAK JAGO publicity campaign to enable citizen-consumer to get their medicines tested free of cost.

Further processing of the samples at the NCP: It is proposed that a Nodal Contact Point (NCP) shall be identified in each State and Union Territories willing to participate in the study either from the State Government organizations or a registered renowned NGO from the State, which has all the required infrastructure and man power to handle the complete process of collection, coding, storage, data keeping and further processing of the samples collected for testing as stated and finalized by experts responsible for conducting the study.

- All Samples will be codified suitably to identify in a proper manner.
- All the samples will be segregated & numbered as per the Generic Name, Brand Name & the manufacturer's name.
- All the respective manufacturers will be contacted with a request to authenticate their products by physical verification of the sample at the NCP to identify the suspects.
- All the suspects and some of the randomly chosen samples will be sent to designated NABL or approved testing laboratory for testing and reporting in the manner decided by the experts of the study

Analysis of the results & preparation of report

- All the results to be collected in a Central Place & analyzed for significance by a team of experts commissioned for the study and documented for sharing with all the stake holders involved for final comments, prior to publication periodically.

The analyzed data should be prepared in a report form to project the prevailing scenario regarding the extent of spurious drugs and drugs not-of-standard quality present in the distribution channels in the Indian Market.

Communication and media strategy

- All stakeholders involved in the project will execute conflict of interest statement.
- All public appearances and statements will be entertained by the appointed person (Bejon Misra, Founder Head, PSM India)

Proposed Road Map for the pilot study

1. The project approval by the competent authorities will be finalized by March 2013
2. Appointment of project leader, coordinators, statistician, experts for preparation of protocols and imparting necessary Training to the Members of the Civil Society & Regulatory Officials will be completed by April 2013
3. Sampling as per the design will be completed within a span of 2 months (May & June) 2013
4. Processing of the samples at the NCP will be completed By July 2013
5. Analysis of all the samples will be completed by September 2013
6. Computation of analytical data & preparation of the report by November 2013.

PROPOSED FUNDING FOR THE STUDY

It is proposed that the funding for the study should be contributory and voluntary based on role and responsibility. All concerned stakeholders shall be contacted to support the study in their own small manner.

Central Drugs Standard Control Organisation (CDSCO) and Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India is expected to be the key contributor by providing technical and financial support to the extent possible. All interested parties shall be approached to contribute towards the study. In this project, for the first time, even consumers will be requested to contribute by donating their medicines to be tested, which they use regularly for treatment. Government agencies, private hospitals, retailers, dealers and medical practitioners dealing with sale or free sampling of medicines will also be requested to donate medicines from their stores to get tested under this study. It is also proposed that a joint consultation will be organised with potential donors to contribute towards the study so that all the stakeholders get involved and commit publicly on their contribution towards the total expenditure as a gesture of involvement and ownership towards the study.

The coordination and management of the study will vest on a Group of Experts nominated by Government of India within their officials, Board Members of PSM India Initiative and Industry Associations, in a transparent manner to ensure unbiased and non-discriminatory approach in conducting the study. ***The detailed budget shall be finalised only after deciding on the total sample size and the statistically accurate methodology in collecting samples from the various clusters.***

PROTOCOLS

- **Roles and responsibilities of experts and stakeholders**
- **Sample collection protocol**
- **Selection of accredited and approved labs**
- **Criteria for codification and physical verification**
- **Protocol for nodal contact point**
- **Documentation**
- **Conflict of interest declarations.**

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