

**NATIONAL
DRUG SURVEY**
2014 - 2016

Preface



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The Indian Pharmaceutical Industry is presently the third largest in the world (volume wise). In terms of value, the size of the industry is approximately Rs. 200,000 Crores (USD 30 billion), out of which more than half is exported to different countries across the globe. The Indian Pharmaceutical sector has shown an exponential growth over last 10 years. The growth of the sector over a short period of time has thrown up challenges for up scaling the regulatory structure in the country. Availability of quality medical products, especially drugs is important from the perspective of health of the consumers. NSQ drugs may lead to not only sub-therapeutic dosage, but also give rise to anti-microbial resistance which is a major health concern.

With such a large domestic pharmaceutical market, circulation of Spurious and Not of Standard Quality Drugs (NSQ) can lead to grave and adverse consequences for both consumers and Drug manufacturers. Spurious and NSQ Drugs is a patient safety issue as it can challenge quality of treatment, lead to emergence of drug resistance, spread of diseases and cause economic burden on the society. It is a shared responsibility of all stakeholders to tackle the challenges of Spurious and NSQ Drugs.

In March 2014, a project report prepared by National Institute of Biologicals (NIB) was submitted to the Ministry of Health & Family Welfare, Government of India to carry out a National Survey for estimation of the extent of problems of Spurious and NSQ Drugs in the country. In April 2014, the Ministry of Health & Family Welfare accorded in principle approval for undertaking the Survey under the overall supervision and guidance of the Director, NIB (*Annexure-1*) and subsequently, on 28th July 2014, the Ministry approved the conduct of the all India Survey in the country at an estimated cost of Rs. 8.5 Crore (USD 1.25 million). (*Annexure-2*).

To plan and undertake this National Drugs Survey, the NIB constituted a Core Expert Committee, a Consultative Expert Committee and a Statistical Design Committee with their Terms of References. A unique, innovative and cost effective AKS-Drug Survey Software was developed in-house at NIB to facilitate collection, collation, segregation, analysis and retrieval of Drug Survey data. The software mapped sampling activities of the Sample Drawing Officers (SDOs) in the field and facilitated track and trace of drugs samples at various stages of Drug Survey.

The execution of the Drugs Survey began with a Pilot Study in the National Capital

Region (NCR) in January, 2015. This study was statistically designed by the Indian Statistical Institute (ISI), Hyderabad. In all, 212 samples were drawn from 37 retail outlets and subjected to test/analysis at the Indian Pharmacopoeia Commission (IPC) Laboratory at Ghaziabad. Four samples were declared NSQ and none was found to be spurious. Feedback from the Pilot Study was used to improve Drugs Survey design, Data Collection Forms and AKS-Software.

Thereafter, the main countrywide Drug Survey was rolled out across the country in April, 2015 and 47,954 samples were drawn from retail outlets, Government Sources and Ports by 932 Sample Drawing Officers (SDOs) from States/UTs and 13 from CDSCO. All the 47,954 samples received at NIB were physically examined by trained Drugs Inspectors of CDSCO. Of these, 47,954 samples drawn under the Survey, 633 samples (1.32%) were found to be out of list of the selected 224 molecules. Further, 309 Drugs samples (0.64%) were found either damaged or lost in transit. These samples were retained at NIB and the balance 47,012 Drugs Samples were subjected to test & analysis as per the prescribed Pharmacopoeia and sent to 10 Central /State Government Drugs Testing Laboratories in accordance with the decision taken by the Ministry of Health & Family Welfare, Govt. of India.

Based on a review of 47 Global Drugs Quality Surveys published between 1992-2015, it was found that this Survey had several unique features. Firstly, the statistical design of the main Drug Survey included as many as 224 Drug molecules belonging to 15 different therapeutic categories of National List of Essential Medicines (NLEM) 2011. Secondly, as part of this Survey, 47,954 drug samples from 23 dosage forms in 654 districts of 36 States and Union Territories were drawn. Thirdly, IT driven AKS software exclusively developed in-house at NIB to monitor activities of the Survey. Fourthly, a nationwide training in drugs survey methodology was imparted in 28 centres to more than 1800 Sample Drawing Officers (SDOs) and representatives of Civil Society / Pharmacy Council of India (PCI). The role of the Civil Society / Pharmacy Council of India (PCI) representatives was to observe the process of drawing drugs sample by SDOs in accordance with the sampling methodology. An animated training module was specially prepared to facilitate the training. Fifthly, the Survey covered the legitimate supply chain which included drawing of 33,656 samples from 5717 Retail Outlets, 8369 samples from 1421 Government Sources and 4987 samples from 8 air/sea ports. It is pertinent to mention that 38.8% of the samples were drawn from rural areas of villages and Taluk Headquarters. Sixthly, all the samples were subjected to test / analysis as per pharmacopoeia requirements.

This report summarizes major findings of the Survey with respect to Spurious and NSQ Drugs in the country, identifies possible causes of the problems and recommends the strategies and implementation plans to address the issues.