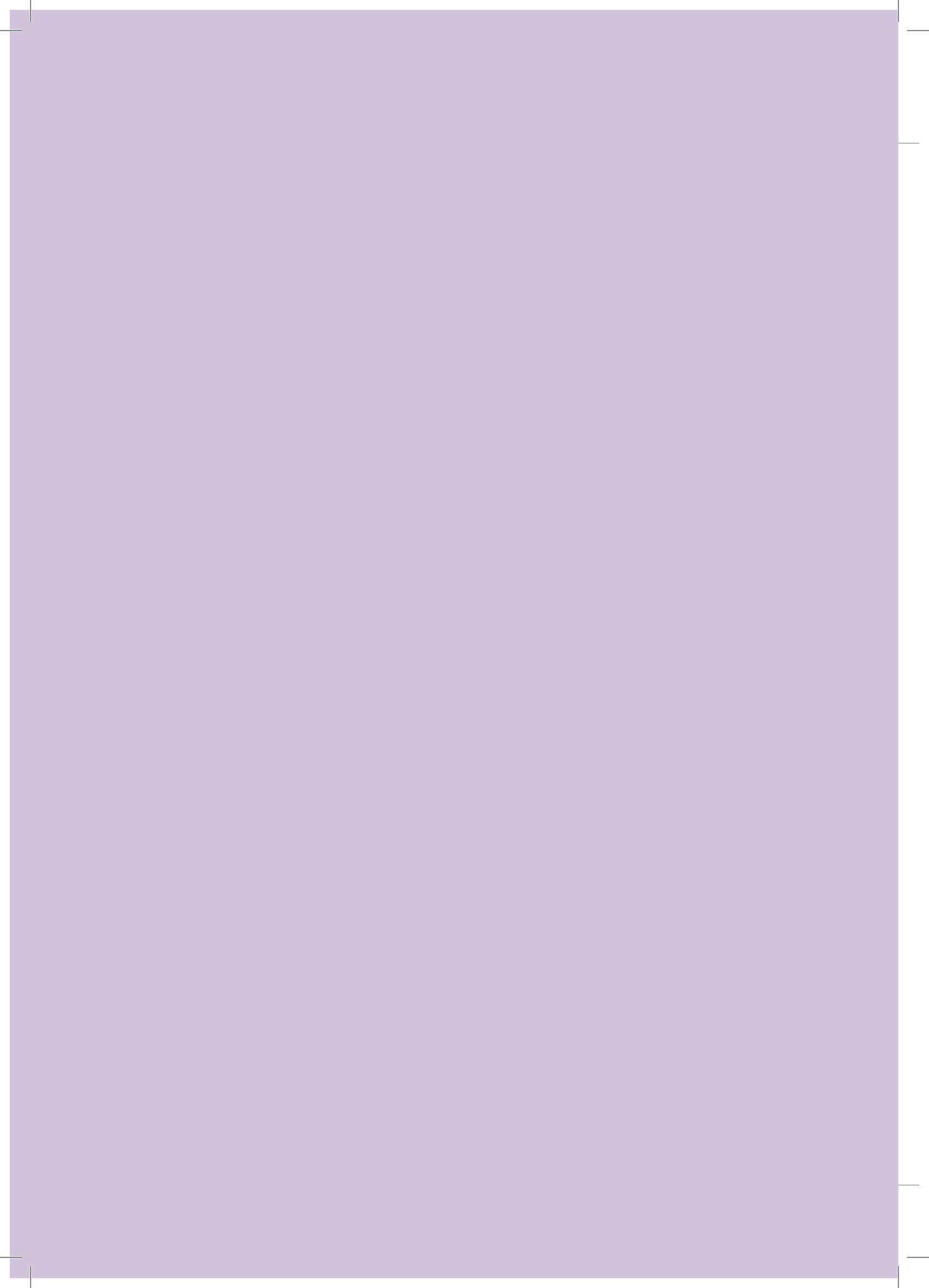


**NATIONAL
DRUG SURVEY
2014 - 2016**

Chapter 4

Conceptualisation





Conceptualisation

The conceptualisation, conduct and coordination of the Survey was carried out by the eminent experts from both public and private sectors. The apex body known as the Drugs Survey - Core Expert Committee's role was planning and designing of the study, preparation of guidance document, preparation of checklist and identification of representatives of Civil Society /Pharmacy Council of India. The Committee also undertook training of Central and State Drug Inspectors and representatives of Civil Society /Pharmacy Council of India. The Core Expert Committee was supported by the Drugs Survey - Consultative Expert Committee. The Drugs Survey - Statistical Design Committee approved the statistical design for Drug sampling. The Drugs Survey - Ethical Committee looked into test and analysis reports of the Drug Survey samples.

Exhibit 4.1
Major Committees of Drug Survey



ETHICAL AND LEGAL CONSIDERATIONS

The Survey of Extent of Problems of Spurious and NSQ Drugs in the Country was conceptualised to generate true picture of the ground reality while avoiding any possible source of error in the estimation of Spurious and NSQ Drugs. Therefore, the Core Expert Committee of the Drug Survey adopted and promoted highest ethical standards among all stakeholders in all actions pertaining to this Survey. Immediately after the constitution of Committee, every member was asked to sign a Conflict of Interest and Confidentiality undertaking to insulate the study from any vested or commercial interest. Further, all stakeholders involved directly or indirectly with the Survey also signed this undertaking. All persons involved in the Survey affirmed:

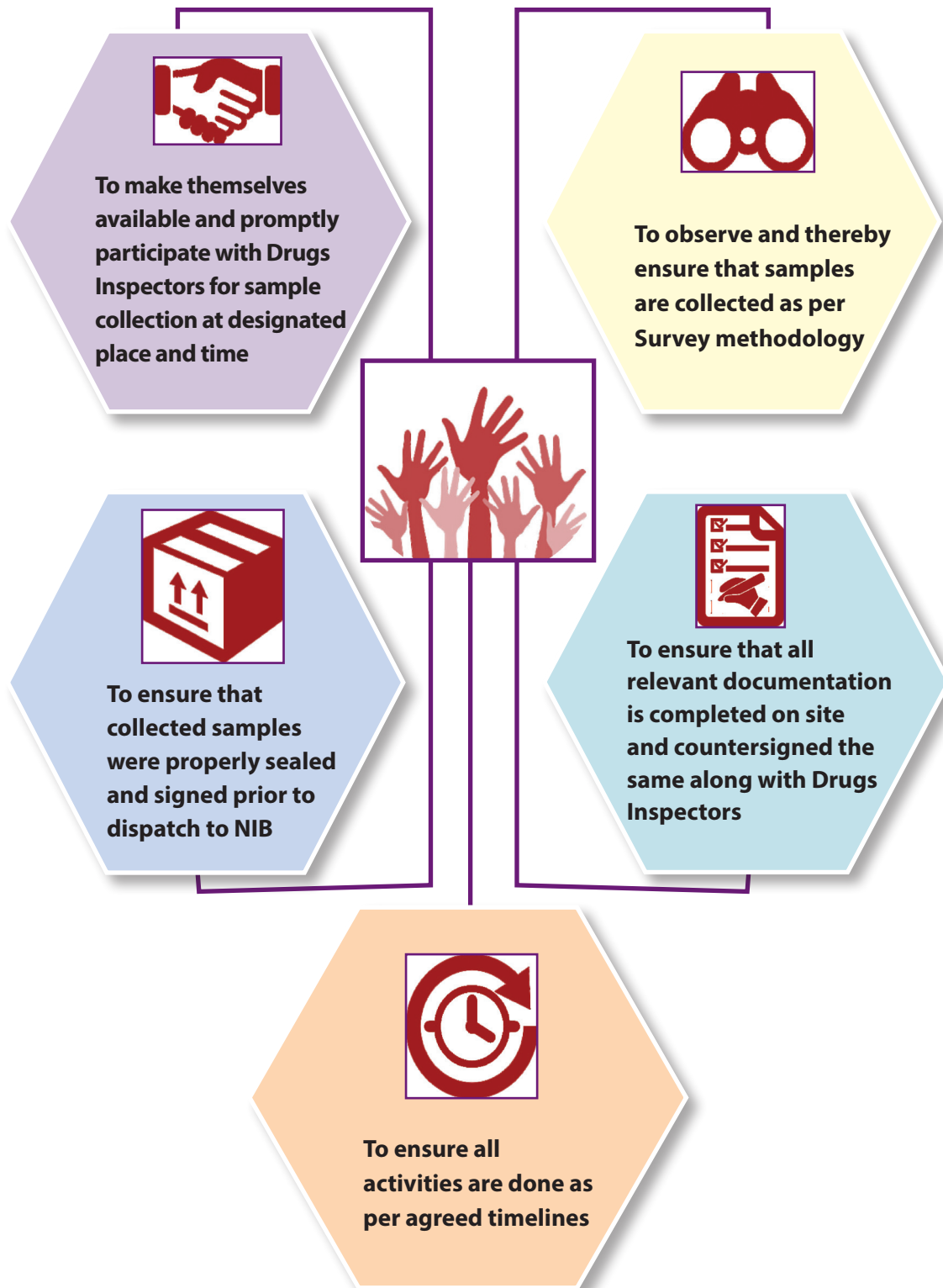
- To treat all information pertaining to Survey as confidential and proprietary to NIB / CDSCO / Ministry of Health & Family Welfare, Govt. of India, the aforesaid parties collaborating with NIB or the aforesaid third parties as the case may be.
- Not to use the information for any other purpose than discharging their function in the above mentioned Survey and all its related activities.
- Not to disclose or provide the information to any person who is not bound by similar obligations of confidentiality.
- Not to disclose any information to print / electronic media or on social networking sites.
- That they have no vested commercial interest / any other conflict of interest in obtaining access to any part of the information which will be generated in this Survey.
- To promptly advise NIB of any change in the above circumstances, including if any issue arises during the course of their activities.

This Survey was intended to have a realistic assessment of the quality of Drugs moving in the domestic market. To instil credibility and transparency in the Survey in general and sampling methodology and sample collection in particular, in addition to the State and Central Drugs inspectors, representatives of Civil Society /Pharmacy Council of India were also involved in the sample collection process as observers (Exhibit 4.2).

To bring further transparency in sample collection and information dissemination, a coding procedure was adopted for the collected samples so that each sample could be traced back to its collection Source and to the Sample Drawing Officer



Exhibit 4.2 The Roles and Responsibilities of the Representatives of Civil Society And Pharmacy Council of India



who collected it. Further, a unique Drug Survey AKS software was developed indigenously to facilitate collection, collation, segregation and analysis of the data collected during the Drugs Survey. This software served as an interface through which status of each sample could be tracked at all times. Software also ensured audit trail and consequently maintained data integrity. Further, limited information related to samples was forwarded through AKS software to laboratory personnel who were blinded to information other than required for testing of drug samples.

Sample Drawing Officers were trained to impart them with skills to gain trust and build the confidence of the retailers during collection of the samples. They were also asked to share purpose of the Survey and seek cooperation from the pharmacists/proprietors of the outlets. In this regard a circular was issued by the Director, NIB (Exhibit 4.3).

As soon as any sample was found to be NSQ or Spurious during lab testing/analysis, NIB, as National Coordinating Centre, communicated the same to the Drug control authorities immediately so that they could make their own legal investigation in accordance with the law.



Exhibit 4.3

राष्ट्रीय जैविक संस्थान
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

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No. H.1-5/2014-NIB

Dated : 17.02.2015

CIRCULAR

Subject : **Survey of Extent of Problems of Spurious and Not of Standard Quality (NSQ) Drugs in the country**

{Kind Attention : Source Owners}.

The Ministry of Health & Family Welfare, Govt. of India has entrusted the conduct of, "Survey of Extent of Problems of Spurious and Not of Standard Quality (NSQ) Drugs in the country", to National Institute of Biologicals (NIB), Noida, U.P. The study is jointly undertaken by Drug Control Officials and Civil Society Representatives (NGO) / Pharmacy Faculty. The team is approaching your source like retail outlets, Govt. hospitals and dispensaries and ports to collect the drug samples under survey. The members of the team have been imparted training and will draw samples as per the methodology and statistical design prepared by the National Survey Sample Office of India (NSSO) and Indian Statistical Institute (ISI) - Kolkata/Hyderabad, Ministry of Statistics and Programme Implementation, Govt. of India.

Please note that these are not legal samples drawn under Drugs & Cosmetics Act and Rules, but are for survey for the purpose of this study. Govt. is going to make payment for drugs samples drawn from retail outlets. The Sample Drawing Official (SDO) and the NGOs / Pharmacy Faculty will make every effort to collect samples without hampering your normal business.

We request you to extend all the normal courtesies for this project of national importance. Let us join hands to assure quality of medicine for people of India.

Thanking you in advance for your kind cooperation.

Yours sincerely

(Dr. Surinder Singh)
Director-NIB &
Chairman – Drugs Survey

