NATIONAL DRUG SURVEY 2014 - 2016

Glossary

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Drug: As per section 3 (b) of Drugs and Cosmetics Act,1940 Drug includes-

i. all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

ii. such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

iii. All substances intended for use as components of a Drug including empty gelatin capsules; and

iv. such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

Spurious Drug: As per section 17(B) of Drugs and Cosmetics Act, 1940 a Drug shall be deemed to be Spurious -

a. if it is manufactured under a name which belongs to another Drug; or

b. 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

c. if 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

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.

Not of Standard Quality Drug: For the purpose of Drug Survey, a Drug is considered to be Not of Standard Quality if it does not comply with the Standards of Quality as specified in Section 16 of the Drugs and Cosmetics Act, 1940 read with Second schedule of the said Act.

Therapeutic Category: Therapeutic category of a Drug is its therapeutic area/ category as mentioned in the National List of Essential Medicines (NLEM)-2011 of India.

Dosage Forms: For the purpose of this survey, dosage forms are pharmaceutical Drug products in the form in which they are marketed for use such as, tablets, capsules, syrups, injections, etc.

Formulations: Under each Drug Molecule, there are a number of generic as well as branded Drug products available in different strengths and different dosage forms. These Drugs are referred to as formulations under the Drug Molecule.

Distinct Formulations: Formulations are considered distinct if any of the four following conditions holds:

a. Brand names of the formulations are different

b. Strength/concentration of the formulations are different

c. Batch numbers of the formulations are different

d. Manufacturers of the formulations are different

Generic and Brand Name: For the purpose of this survey generic name of a Drug is the name given under pharmacopoeia whereas brand name is the trade name selected by the manufacturing company. For example, Paracetamol is the generic name whereas Calpol and Crocin are the two popular brand names given by the manufacturers.

Active Pharmaceutical Ingredients or Bulk Drugs: As per Drug Price Control Order (DPCO) 2013 Active Pharmaceutical Ingredients or Bulk Drugs mean any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards

specified in the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation

Drugs Consultative Committee: As per Drugs and Cosmetics Act, 1940 Drugs Consultative Committee is constituted by Government of India to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout (India) in the administration of this Act.

Drug Molecule: For the purpose of the survey, Drug molecule is the active pharmaceutical ingredient of any medical product.

Drug Molecule ID: Each of the 224 Drug molecules selected for this Drug Survey are identified by a unique code. This unique code is called Drug Molecule ID (DMID)

Sample: Drugs collected by the team of Sample Drawing Officer and representative of Civil Society /Pharmacy Council of India from various sources as per the Drug Survey plan are called samples.

Sample ID: For the purpose of this Survey, each sample drawn under the survey was assigned a unique ID for identification and traceability. This ID is called Sample ID.

Sample Drawing Officers: The Centre/State Drug Inspectors were the Sample Drawing Officers for the survey.

Nodal Coordinating Officers: The State Drug Controllers were the Nodal Coordinating Officers of the Drug Survey to ensure efficient and smooth conduct of the survey in their respective States/Union Territories.

Sample Size: Sample size refers to total quantity of sample collected during the Drug Survey.

Adequate Quantity: Minimum required quantity of samples of each dosage forms required to perform all the pharmacopoeial tests is referred to as adequate quantity.

Minimum Primary Packaging Unit: Minimum primary packaging of each dosage form is called minimum primary packaging unit. This may be a strip for tablets, may be a strip for capsules or may be bottle of capsules and so on. For example, a half strip or an open bottle of capsules will not be considered as minimum primary packaging unit.

Seal: Seal refers to brass seals used during this survey. A Seal with a unique number was issued to each Sample Drawing Officer.

Data Form: Data form refers to the form which was developed and given to Sample Drawing Officers for recording of particulars of Drug sample and sample Source.

Random Number: A number was specified in the data form in the last row of each column where details of formulations were recorded. This is called a random number and it was used for random selection of formulation.

AKS Software: An indigenous software developed by the software development team of NIB to facilitate collection, collation, segregation, analysis and retrieval of the data collected during the Drugs Survey.

Sources: sources refers to various sources of Drugs from where samples were collected for the Drug Survey. This includes Retail Outlets, Government sources and notified Ports.

Government Sources: Government sources refer to public sources from where samples were collected for the Drug Survey. These include Civil Hospital Stores, State Government Medical Store Depots and CGHS/ESI Dispensaries.

Retail Outlets: For the purpose of this study, Retail Outlets are those that have been licensed by respective State Licensing Authorities to sell Drugs.

Ports/Notified Ports: Refers to Ports notified by the Government for import of Drugs.

Pilot Study: For the purpose of this Survey the pilot study was conducted to validate study design, predict an appropriate sample size, statistical method, identify possible gaps and difficulties which may be encountered in the full scale study. The feedback from the pilot study was used to improve the main study design, data collection forms and digital technology tools.