CHAPTER – 2

METHODOLOGY
AND
APPROACH
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2 The Universe / Population & Sampling:

To ascertain whether, workers continuously working in the pharmaceutical and bulk drug industries acquire any occupational microbial diseases either due to the side effects of the chemicals, working environment or due to unhygienic working conditions resulting in to the microbial infections, allergies or chronic diseases and also to ascertain whether treated effluents released in either common effluent treatment plant or open landscape create any health related issues in the community and in animals residing in the nearby area particularly microbial infections, primary sample data from 40 Pharmaceuticals / bulk drug industries located in and out skirts of Bharoach, Ankleshwar, Vapi, Valsad, Vadodara, Surendranagar and Ahmedabad was collected and the workers working in these units were consulted by set of questions developed for the given purposes.

2.1 Primary Data

To collect the information from various stake holders, a survey form was developed and the data related to the health from workers working in different departments, active trade unions, personal department, employers of pharmaceutical and bulk drug units etc. was collected. The summary details of survey form are enclosed as Annexure IV.

2.1.1 Overall details of the Unit:

In pharmaceutical industries i.e. Formulation units or Bulk Drug units, Stores, Quality Control, Manufacturing, Effluent Treatment plant, D.M. water treatment Plant, Chilling Plant and Packing departments are functional. The precise format of questionnaire was prepared keeping the various departmental activities under taken
by pharmaceutical / bulk drug industries enabling to generate data of workers working in these departments. The questionnaire include following details;

1. Name and address of Pharmaceutical unit
2. Type of manufacturing products Liquid oral/ Tablets/
   Capsules/Injections/Ointments/Bulk drugs
3. Total Number of employees: (Male / Female)
4. Number of employees working in Manufacturing process /activities: (Male / Female)
5. Number of employees working in Quality Control / Quality Assurance
department: (Male / Female)
6. Number of employees working in Packing department: (Male / Female)
7. Number of employees working in D.M. Plant / department: (Male / Female)
8. Number of employees working in Store / Material Dispensing department:
   (Male / Female)
9. Details of health aspects of the workers working in the Effluent treatment
   Plant / Department (Male / Female)
10. Details of health aspects of the workers working in the Chilling Plant / Air
    conditioning plant (Male / Female)

2.2. Data collection from Individual workers related to health:

The informative data from workers working in the different departments in these 40 pharmaceutical / bulk drug units with respect to their health and whether they have contracted out any microbial infection / diseases due to prolonged working (Since last three years) was collected as under..

1. Name of the Worker
2. Working Since last three years
3. Name of the department where worker is working
4. Sick leaves availed in last three years
5. Reasons for the sick leaves
2.3 Data collection from Trade Unions having membership in Pharmaceutical industries regarding health of workers:

The Trade unions\textsuperscript{13} active in these pharmaceutical / bulk drug units were consulted with respect to health and whether they have any data or survey of workers / any employees who have contracted out any microbial infection / diseases due to prolonged working (Since last three years) in these units was collected as under.

1. Name of the Trade union / Employee's Association
2. Membership Since last three years
3. Name of the Pharmaceutical unit and department
4. Sick leaves availed in last three years
5. Reasons for the sick leaves

2.4 Data collection from Employers / Personal department in Pharmaceutical industries regarding health of workers:

The informative data from the Employers / Personal department\textsuperscript{14} of these 40 pharmaceutical / bulk drug units with respect to health and whether workers / any employees have contracted out any microbial infection / diseases due to prolonged working (Since last three years) in these units was collected as under.

1. Name of the Pharmaceutical unit and department
2. Sick leaves availed in last three years
3. Reasons for the sick leaves

\textsuperscript{13} The Trade Union registered under the provisions of the Trade Union Act, 1926

\textsuperscript{14} The department in establishment looking after compliances of working conditions of employees
2.5 Data collection with respect to Effluent treatment Plant:

The informative data from the Employers / Personal department of these 40 pharmaceutical / bulk drug units with respect to whether unit has own Effluent treatment Plant\(^{15}\) or so was collected as under.

1. Whether Company has own Effluent treatment Plant or releasing the effluent in common effluent treatment plant of G.I.D.C?
2. The details of Biological Oxygen Demand (B.O.D.) and Chemical Oxygen Demand (C.O.D.) of treated water.

2.6 Data collection with respect to coverage of health aspects of the workers under either the Employees State Insurance Act, 1948 or any other medical insurance scheme:

The informative data from the Employers / Personal department of these 40 pharmaceutical / bulk drug units with respect to whether the workers have been covered under the health insurance or so was collected as under.

1. Whether Company is registered under Employees State Insurance Act, 1948
2. If, yes details of claims with respect to any microbial infection / diseases due to prolonged working (Since last three years) in these units under the ESI Act, 1948.
3. Whether the Company has Medical Insurance?
4. If, yes details of claims with respect to any microbial infection / diseases due to prolonged working (Since last three years) in these units under such medical insurance.

The informative data from the Panel Doctor (If any ) on duty of these Pharmaceutical / bulk drug units was collected with respect to any microbial infection / diseases due to prolonged working (Since last three years) in these units.

\(^{15}\) Effluent treatment plant for treatment of wash / drain effluent in establishment before release to main stream
Details of implementation and compliance of the labour laws having expressive provisions related to Health and Welfare of the workers under the provisions of the Factories Act, 1948 and the Contract Labour (Regulation and Abolition) Act, 1970 was collected.

2.7 Secondary Data:

Details of occupational diseases acquired and related data from the Employees State Insurance Corporation under the provisions of the Employees State Insurance Scheme Act 1948

The secondary data from the Employees State Insurance Corporation under the provisions of the Employees State Insurance Scheme Act 1948 and case study under the provisions of the Workmen’s Compensation Act, 1923 was collected as under.

1. Details of Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries as identified by ESIC in Gujarat, if any.
2. Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries treated in ESIC hospitals / dispensaries in Gujarat.
3. Details of remedial measures recommended to safe guard against such identified Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries.
4. Number of ESIC hospitals and dispensaries in Gujarat with location addresses.
5. Number of pharmaceutical and bulk drug industries registered under the ESIC and Number of workers covered working in such units.
6. Amount of contribution collected from employers and employees during last three years from pharmaceutical and bulk drug industries and workers from various ESIC notified area in Gujarat.
2.8 Details of Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries as identified by National Institute of Occupational Health (NIOH) in India and Gujarat.

The secondary data from the National Institute of Occupational Health (NIOH)\textsuperscript{16} which is traditionally focused on under-served workers and those without access to occupational health care, in addition to providing a referral centre for access to expertise in a wide variety of occupational health disciplines was collected as under.

1. Details of Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries as identified by National Institute of Occupational Health (NIOH) in India and Gujarat, if any.
2. Details of study in progress for identifying Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries by National Institute of Occupational Health (NIOH) in India and Gujarat.
3. Details of remedial measures recommended to safeguard against such identified Occupational microbial diseases to the workers in pharmaceutical and bulk drug industries
4. Details of publications with this regard.

2.9 Details of incidences having taken place where discharge of untreated water has damaged the nearby society at large.

The secondary data regarding implementation of standards for releasing the treated effluent, as fixed by the Gujarat Pollution Control Board\textsuperscript{17} was collected as under.

1. Details of number of effluent treatment plants functionally located district wise in Gujarat.

\textsuperscript{16} National Institute of Occupational Health (NIOH)—Research organization—Government of India for study and research in field of occupational diseases contracted out to the workers based at Ahmedabad.

\textsuperscript{17} The Gujarat Pollution Control Board—implements GPCB Act and looks after the pollution caused by industrial establishment
2. Standard of Biological Oxygen Demand and Chemical Oxygen Demand fixed before release of treated water in Pharmaceutical and Bulk drug units.
3. Norms and Number of inspections carried out, compliance and cases filed under the provisions of the GPCB Act in Pharmaceutical and Bulk drug units.
4. Details of incidences having taken place where discharge of untreated water has damaged the nearby society at large.

2.9.1 Details of implementation of the Factories Act, 1948, Hygiene Laboratory under the Directorate of Industrial Safety and Health and the Contract Labour (Regulation and Abolition) Act, 1970

The secondary data regarding implementation of provisions of existing labour laws related to health, welfare and safety of workers in pharmaceuticals and bulk drug units was collected as under.

1. District wise details of Pharmaceutical units registered under the Factories Act,1948 18 and workers working in such units as on 1/12/2010 (last five years)
2. District wise details of bulk drug manufacturing units registered under the Factories Act,1948 and workers working in such units as on 1/12/2010(last five years)
3. Details of function rendered by Hygiene Laboratory study undertaken with its findings of last five years in Pharmaceutical units and bulk drug manufacturing units with respect to Health, Welfare and Safety of the workers working in these units.
4. Details of Microbial Occupational diseases identified during last five years, with name of unit, district and number of workers affected.

18 An Act (63 of 1948) to consolidate and amend the law regulating labour in factories.
5. Number of fatal and non-fatal accidents occurred during last five years in Pharmaceutical units and bulk drug manufacturing units. (District and year wise, number of workers affected, compensation awarded and cases filed)

2.9.2 Details of compliance of the provisions related to Health and Welfare of the workers under the provisions of the Factories Act, 1948 and the Contract Labour (Regulation and Abolition) Act, 1970 was collected.

1. Norms and number of Inspections carried out, compliance and court cases filed during last five years in Pharmaceutical units and bulk drug manufacturing units with respect to Health, Welfare and Safety of the workers working in these units under the provisions of the Contract Labour (Regulation and Abolition) Act, 1970\textsuperscript{19} was collected.

\textsuperscript{19} An Act (37 of 1970) to regulate the employment of contract labour in certain establishments and to provides for its abolition in certain circumstances and for matter connected therewith.