CHAPTER V

QUALITY CONTROL MEASURES IN THE MANUFACTURE OF DRUGS

INTRODUCTION

The issue of drug safety and quality was pitchforked into the limelight in 1961 after the “Thalidomide disaster”, when thalidomide was prescribed as a sedative to be used widely by pregnant women to offset morning sickness. What followed was a disaster. Babies born to these women had ‘seal limbs’. It was a kind of congenital deformity. Babies are born with defective or rudimentary hands and feet. Nearly half a century has passed since the first thalidomide children were born. In the wake of that disaster stricter controls were imposed on the manufacture and sale of medicines throughout Europe. In England such regulations are now governed by the Medicine Act 1968.

In early 1937 the United States enacted the first comprehensive drug regulatory law after the death of 107 people due to the consumption of a drug used in treating common infection. However, this concept of safety and quality of drug still remains utopian in several developing countries including India. Justice Lentin Commission which looked into the JJ Hospital glycerol tragedy in Mumbai,

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1 Food, Drug & Cosmetic Act 1938 which was codified in 21 USC §301-392 (1976) as amended from time to time.
in which 14 people died after glycerin was intravenously administered to patients, found that the glycerin was adulterated with diethylene glycol - a toxic chemical which converted the drug into industrial grade glycerin.

Several such instances exposed the loopholes in the system of regulating drug manufacture and enforcing safety standards. Only a few spectacular instances of wrong medication and defective medicine find their way into the media. There may be scores that go undetected, especially in small towns and rural areas.

The problem both in terms of quality and quantity is enormously complex and has several dimensions. Therefore, one cannot resort to generalisations or over simplified solutions. The concept of drug safety and quality assumes importance in the light of large-scale illiteracy and ignorance of the people.

Pharmaceutical products involve complex mixtures of ingredients. Manufacture of these products require application of secret scientific findings. It is very difficult for a consumer to judge its quality when these are manufactured on a massive scale. The complexity of the product and frequent changes in the formulations and in designs of the product makes it difficult for enforcement agencies to regulate its quality. May be because of this reason, there is little case

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2 See generally, Report of commission of inquiry (1988). It was appointed by the Government of Maharastra was headed by Justice Lentin of Bombay High Court. It submitted its report in March 1988.

3 See The Hindu, July 28, 1991 for details of other incidents that took place in India. Also see Indian Express, May 26, 1998 at p. 12.
law in India on the subject. These changes also make the product susceptible to incorrect use and misuse.

It is proposed to discuss various provisions of the Drugs and Cosmetics Act 1940 dealing with standards of drugs, good manufacturing practices, provisions dealing with prohibition of manufacture and importation of misbranded, adulterated and spurious drugs, powers and responsibilities of the inspectors and provisions dealing with penalties. It is also intended here to deal with other civil remedies that would be available to the drug injured claimants in the light of the special plans devised in the developed countries to overcome the difficulties posed by the tort law solutions.

Indian Constitution included improvement of public health as one of the primary duties of the State.\(^4\) Basing on this provision Supreme Court has carved out the State’s obligations to enforce production of qualitative drugs and elimination of injurious ones from the market.\(^5\) When Constitution of India came into force, regulation and control of manufacture, sale and distribution was

\(^4\) Constitution of India, Article 47 reads:

“Duty of the State to raise the level of nutrition and standard of living and to improve public health. The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as its primary duties and ....”

included in the Concurrent List. Consequently the central law still continues to
govern the subject.

Quality control over drugs is made under the provisions of Drugs &
Cosmetics Act 1940 and the Drugs & Cosmetics Rules 1945. In view of the
importance of the subject, the law has been amended from time to time to ensure
that uniform standards are maintained throughout India. These amendments
empowered the Central Government to control the manufacture of drugs, to
appoint inspectors for taking samples and inspecting manufacturing units and to
appoint government analysts. India has a federal structure of government and
therefore, the responsibility for enforcing the regulating provisions are divided
between central and state governments. The state governments are responsible for
exercising control over drugs manufactured, sold and distributed in their respective
states.

Scheme of the Drugs and Cosmetics Act

The basic legislation enforced by the Drug control department is the Drugs
and Cosmetics Act 1940. This statute gives the drug control agencies in the
country the general regulatory authority over drugs and cosmetics. The agencies
have very wide powers with respect to drugs. The import, manufacture and sale of
adulterated and misbrand drugs are prohibited. Standards relating to content and
process of manufacture are set and label and warning requirements are imposed.

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In this area, the regulatory agencies have extensive powers of licencing and inspection. All new drugs must be supported by extensive laboratory research and testing and by reports indicating efficacy and safety. After approval, the regulating agency may revoke its acceptance of a new drug if further information leads to the conclusion that the drug is unsafe or ineffective. If the original application contained an untrue statement of material fact again the licence can be revoked.

In addition to the ordinary inspections of manufacturing process, the administration is also empowered to maintain strict controls over special drugs like antibiotic drugs. Each batch of such drugs produced must be inspected and certified by the agency. No such drugs may be sold unless the batch in which it was produced has met requirements with respect to identity, purity and strength.

In exercise of the powers conferred by the Act, the department of the Ministry of Health and Family Welfare of the Central Government can make rules. But under the provisions of the Act, the Drugs Technical Advisory Board has to be consulted before any rule is amended or introduced. The Drugs Technical Advisory Board is a technical body with the Director General of Health Services as the chairman and Drugs Controller of India as the member-secretary. The Board includes inter alia president of Medical Council of India, president of

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7 See Drugs and Cosmetic Rules 1945 Rule 78 and 78 A, from 28 and 28.A in Schedule.A and also see Schedule F and F(1).
Pharmacy Council of India, representatives of the Indian Medical Association, Indian Pharmaceutical Association, pharmaceutical industry, as well as state drug controllers and government analysts.

**Drugs standards**

Under the Act, Indian Pharmacopoeia is the sole book of standards for drugs manufactured in India. However, for drugs for which no standards have been provided in Indian Pharmacopoeia, standards laid down in other pharmacopoeias are applicable. For compiling and revising standards in Indian pharmacopoeia, a permanent Indian Pharmacopoeia Committee is constituted. Similar standards are made applicable to drugs imported into India.

Similarly for drugs intended for veterinary use, the standards should be those given in the latest edition of the British Veterinary Codex. The standards for patent and proprietary medicines should be those laid down in Schedule V and such medicines should also comply with the standards laid down in the Second Schedule to the Act. For instance, the test for disintegration to be complied with by the manufacturer of patent or proprietary medicines in the form of tablets intended to be swallowed is that it should disintegrate in not more than thirty

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8 See supra n.6, section 16 and Second Schedule.
9 Authorised pharmacopoeia for the purposes of the Act are the Indian Pharmacopoeia, the Pharmacopoeia of U.S., National Formulary of the U.S., International Pharmacopoeia and the Pharmacopoeia of Russia. Id. Section 3(h).
10 Supra n.7, Rule 124 - A
11 Id., Rule 124 - B
minutes if it is not coated and in not more than sixty minutes if it is sugar coated or film coated. The standards for patent or proprietary medicines containing vitamins for prophylactic, therapeutic or pediatric use should contain the vitamins in quantities not less than and not more than those specified in the table annexed to the Schedule. Schedule R provides for the standards for medicinal contraceptives. The standards which other contraceptive will have to comply with should be in confirmity with the formulae approved as safe and efficacious by the Central Government. Such formulae should be displayed on the label of every container of such contraceptive. Standards for substances intended to be used for the destruction of the vermin or insects which cause disease in human beings and animals should be such as are laid down in Schedule O. Schedule FF lays down the standards for ophthalmic preparations and such preparations should also comply with the standards set out in the Second Schedule of the Act. The Rules also provide for the permitted colours that a drug should contain.

Requirement of Premises, Plant and Equipment

The factory buildings for manufacture of drugs should take such measures as to avoid contamination from open sewage, drain, public lavatory or any factory

12 Id., Schedule V.
13 Id., Rule 125.
14 Id., Rule 126.
15 Id., Rule 126-A.
16 Id., Rule 127.
which provides disagreeable fumes, dust or smoke. The buildings used for the factory should be constructed in such a way to permit production of drugs under hygienic conditions. They should also conform to the conditions laid down in the Factories Act, 1948.

The premises used for manufacturing, processing, packaging, labelling and testing purposes should be compatible with other manufacturing operations that may be carried out in the same or adjacent premises. It should be adequately provided with the working space to allow orderly and logical placement of equipment and materials so as to avoid the risk of mix up between different drugs. It should also control the possibility of cross contamination by other drugs or substances and to avoid the risk of omission of any manufacturing or control step. The buildings must be designed to prevent entry of insects and rodents. Interior surface should be smooth and free from cracks and permit easy cleaning and disinfection. It must be provided with adequate lighting and ventilation and if necessary air conditioning to maintain a satisfactory temperature and relative humidity that will not adversely affect the drug during manufacture and storage or the accuracy of the functioning of the laboratory instruments. Buildings should also be provided with underground drainage system in the processing area. The sanitary fittings and electrical fixtures in the manufacturing area should be

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17 See id., Schedule M inserted by Drugs and Cosmetics (Sixth Amendment) Rules 1988 which came into force from 24th June, 1988 by Vide G.S.R. 735 (E), dated 24th June 1988.
concealed and ventilation and air inlet points should be even with the surface of the wall as far as possible\textsuperscript{18}.

Water used in the manufacture should be pure and of drinkable quality, free from pathogenic micro-organisms. Waste water and other residues from the laboratory which might be prejudicial to the workers or to public health should be disposed of after suitable treatment as per the prevailing requirements of water pollution control to render them harmless\textsuperscript{19}.

**Requirements for manufacturing of sterile products**

For the manufacture of sterile drugs, separate enclosed areas specifically designed for the purpose should provided. These areas should be provided with air locks for entry and should be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply should be filtered through bacteria retaining filters and should be at a pressure higher than that in the adjacent areas. The filters should be checked for performance on installation and periodically thereafter and records of such checks should be maintained\textsuperscript{20}. All surfaces in manufacturing areas should be designed to facilitate clearing and disinfection. Routine microbial counts of all sterile areas should be carried out during manufacturing operations. The results of such counts should be checked against established house standards. Access to the

\textsuperscript{18} Id. Schedule M at para. 1.1.2.

\textsuperscript{19} Id. at para. 1.1.4.

\textsuperscript{20} Id. at para. 1.2.1.
manufacturing areas should be restricted to minimum number of authorised personnel. Special procedures to be followed for entering and leaving the manufacturing area should exhibited. The design of the areas should preclude the possibility of products intended for sterilisation from being mixed with or taken to be products already sterilised. In case of terminally sterilised products the design of the area should preclude the possibility of mix up between nonsterile and sterile products.

The manufacturer should provide adequate working space and adequate room for the orderly placement of equipments and materials used in any of the operation for which it is employed so as to minimise or eliminate any risk of mix up between different drugs, raw materials and to control the possibilities of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises. There should be adequate space in storage areas for materials 'under test'. Arrangements are to be made to allow the equipment to dry, a clean and for to orderly placement of stored materials and products wherever necessary under controlled temperature and humidity.

All the personnel including the temporary staff who come into direct contact with the product or raw materials should undergo periodic health check up. They should be free from contagious or obnoxious diseases. Their clothing

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21 Ibid.

22 Id. at para. 1.2.2.
should consist of white or coloured material made up of cotton or synthetic fabric suitable to the nature of work and climate and should be clean\textsuperscript{23}. Just before entry to the manufacturing area, there should be change room with adequate facility for personal cleanliness, such as clean towels and hand dryers, soap, disinfectant and hand scrubbing brushes so that all personnel change their street clothes and wash and wear clean factory uniform, head gear and footwear before entering the manufacturing area and analytical laboratory. For all workers engaged in filling and sealing of containers of sterile preparations suitable sterile gowns, headgears, footwears and marks made of synthetic fabric should be provided to cover the nostrils and mouth during work\textsuperscript{24}.

The manufacturer should also provide adequate facilities for first aid. There should be provision for medical examination of workers at the time of employment and periodical check up once in a year, with particular attention being devoted to freedom from infectious conditions. There should also be a facility for vaccination or other exigencies. The licesee should provide the services of a qualified physician for assessing the health status of personnel involved in the manufacturing and quality control of drugs\textsuperscript{25}.

The manufacturing area should not be utilised for any other purpose. It should be maintained clean and in an orderly manner free from accumulated

\textsuperscript{23} Id. at para. 1.2.3.
\textsuperscript{24} Ibid.
\textsuperscript{25} Id. at para. 1.2.4.
waste, dust or debris etc. Eating, chewing, smoking or any unhygienic practices should not be permitted in the manufacturing area. A routine sanitation programme should be drawn up and observed which should be properly recorded and should indicate specific areas to be cleaned. Cleaning intervals cleaning procedures including equipment and materials to be used for cleaning is to be indicated. The personnel who are to and responsible for cleaning operations is to be specified. Records of compliance in respect of sanitation should be maintained for inspection\textsuperscript{26}.

Equipment used for manufacture of drugs should constructed, designed, installed and maintained to achieve operational efficiency to attain the desired quality and to prevent physical, chemical and physiochemical changes through surface contact. Facilities for thorough cleaning whenever necessary to minimise any contamination of drugs and their containers during manufacture should also be provided\textsuperscript{27}.

Specific written cleaning instructions for all equipment and utensils should be readily available and the operators are required to be familiar with them. Manufacturing equipment and utensils should be thoroughly cleaned and if necessary sterilised in accordance with the written and specific instructions. When indicated all equipment should be disassembled and thoroughly cleaned to

\textsuperscript{26} Id. at para. 1.2.5.

\textsuperscript{27} Id. at para. 1.2.6.
preclude the carry over of drug residues from previous operations or batches. The accuracy and precision of the equipment used for specific filling should be checked and confirmed at regular intervals and records of such checks should be maintained. The accuracy of premise filling should be checked, confirmed and calibrated at regular intervals and records of such checks should be maintained. Equipment used for sterilisation of drugs should be filled with recording devices so as to monitor and evaluate the performance of the equipment and should be calibrated and checked at regular intervals. Equipments used for critical steps in processing should be monitored by devices capable of recording the permanent parameters or with alarm system to indicate malfunctions. These devices should also be calibrated and tested and records be maintained.

The licensee should keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per law. All such materials should be identified and their containers examined for damage and assigned control numbers. They should be stored at optimum temperatures and relative humidity. They should be conspicuously labelled indicating the name of the materials, control numbers, name of the manufacturer and be specially labelled 'under test' or 'approved' or 'rejected'. They should be systematically sampled by quality control personnel and be tested for compliance with required standards of

28 Ibid.
29 Ibid.
30 See id., Schedule 'U'.
quality and released by quality control personnel through written instructions. These should be so organised that stock rotation is on the basis of the first in and first out principle in storage areas. They should be arranged in such a way that all rejected materials are conspicuously identified and are destroyed or returned to the suppliers as soon as possible and records of it should be maintained\(^{31}\).

**Master formula records**

The licensee should maintain master formula records relating to all manufacturing procedures for each product which should be prepared and endorsed by the competent technical staff that is the head of production and quality control. The master formula records should give the patent or proprietary name of the product along with the generic name if any, strength and dosage form. It has to give a description or identification of the final containers, packing materials, labels and closures to be used. Record must show the identity, quantity and quality of such raw material to be used irrespective of whether or not it appears in the finished product. The permissible average that may be included in a formulated batch should be indicated. The formula should also give a description of all vessels and equipment and sizes used in the process and manufacturing and control instructions along with parameters for critical steps, such as mixing, drying blendings and sterilising the products. The particulars of the formula should show the theoretical yield to be expected from the formulation at different stages of

\(^{31}\) Supra. n.17 at para. 1.2.7.
manufacture and permissible yield limits. The detailed instructions and precautions to be taken in manufacture and storage of drugs and of semi-finished products should be given in the formula. It should also specify the requirements of in process quality control tests and analysis to be carried out during each stage of manufacture including the designation of persons or departments responsible for the execution of such tests and analysis.

The licensee should also maintain batch manufacturing record as per law for each batch of the drug produced. Manufacturing records are required to provide a complete account of the manufacturing history of each batch of a drug showing that it has been manufactured, tested and analysed in accordance with the manufacturing procedures and written instructions as per the master formula.

Manufacturing operations and control

All manufacturing operations and controls are to be carried out under the supervision of competent technical staff approved by the Licensing Authority. Each critical step in the process relating to the selection, weighing and measuring of raw materials, addition during the process and weighing and measuring during the various stages are to be performed under the direct personal supervision of a competent technical staff. Products not prepared under aseptic conditions are

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32 Id., para 1.2.8.
33 Ibid.
34 See Schedule U.
35 Supra. n.17 at para. 1.2.9.
required to be free from pathogens. The contents of all vessels and containers used in manufacture and storage during various manufacturing stages shall be conspicuously labelled with the names of the product, batch number, batch size and stage of manufacture. Labels are to be attached to all mechanical manufacturing equipment during their operation with conspicuous labels bearing the name of the product and batch number$^{36}$.

The licensee should prevent cross contamination of drugs with sex hormones and B.Lactum antibiotics by appropriate methods. These methods may include carrying and manufacturing operations in separate building or adequately isolating the operation by total enclosure within the building and using appropriate pressure differential in the process and providing a suitable exhaust system and designing laminar flow steril air system for steril products$^{37}$.

The germicidal efficiency of UV lamps should be checked and recorded indicating the burning hours or checked by using intensity meter. The water for injection shall be used either immediately or stored to prevent microbial growth at a specified temperature in a jacketted stainless steel storage tank. Individual containers of liquid orals, parenterals and opthalmic solutions should be examined against black or white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matters. Finished tables

\[36 \text{ I.d. at para. 1.2.10.}\]

\[37 \text{ Ibid.}\]
should be inspected for presence of foreign matters besides any other defects. Expert technical staff approved by the Licensing Authority should check and compare actual yield against theoretical yield before final distribution of the batch. All process controls as required under master formula including room temperature, relative humidity, weight variation, disintegration time and mixing time, homogeneity of suspension, volume filled, leakage and clarity should be checked and recorded.

If a product batch has to be reprocessed, reprocessing procedure should be authorised and recorded. An investigation should be carried out into the causes necessitating reprocessing and appropriate corrective measures should be taken for prevention of recurrence. Recovery of product residue may be carried out by incorporating in subsequent batches of the product, if permitted in the master formula.

All containers and closures should comply with the pharmacopoeal requirements. Suitable specifications, test methods, cleaning procedure and sterilisation procedure, when indicated should be used. It should be assured that containers, closures and other component parts of drug packages are suitable and they are not reactive, absorptive or leach to an extent that significantly affects the

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quality. Written schedule of cleaning should be laid down. Cleaning should be
done using deionised water or distilled water\textsuperscript{39}.

**Labels and other printed materials**

Printed packaging materials including leaflets should be stored, labelled
and accounted in such a way to ensure that batch packaging materials and leaflets
relating to different products do not become intermixed. Access to such materials
should be restricted to authorised personnel only. Prior to issue, all labels for
containers, cartons and boxes and all circulars, inserts and leaflets should be
examined and released as satisfactory for use by the quality control personnel. To
prevent packaging and labelling errors, a known number of labelling and
packaging units should be issued and if required be coded. Such issues should be
made against a written signed request which indicates the quantity and the types
required. Before packaging and labelling of a given batch of a drug it must be
ensured that the batch has been duly tested, approved and released by the quality
control personnel\textsuperscript{40}. Upon completion of the packaging and labelling operation, a
comparison should be made between numbering of labelling and packaging units
issued and number of units labelled and packaged. Any significant or unusual
discrepancy in the numbers should be carefully investigated before releasing the

\textsuperscript{39} *Id.* at para. 1.2.12.

\textsuperscript{40} *Id.* at para. 1.2.13.
final batch. Unused coded and spoiled labels and packaging materials should be destroyed.\footnote{Ibid.}

**Records of distribution, complaints and Adverse reactions**

Records for distribution of drug should be maintained for distribution of finished batch of a drug in order to facilitate prompt and complete recall of the batch if necessary.\footnote{Id., at para. 1.2.14.} Reports of serious adverse reactions resulting from the use of the drug along with the comments should be informed to the concerned licensing authority.\footnote{Id. at para. 1.2.15.}

**Quality control system**

Every drug manufacturing establishment should have a quality control department supervised by approved expert staff directly responsible to the management but independent of other departments. The quality control department should control all raw materials, monitor all in-process quality checks and control the quality and stability of finished products. The duties of this department are to prepare detailed instructions in writing for carrying out each test and analysis. It has to release or reject each batch of raw materials and release or reject semi-finished products if necessary. It has to release or reject packaging and labelling materials and the final containers in which drugs are to be packed and decide whether to release or reject each batch of finished product that is ready for
distribution. It has to evaluate the adequacy of the conditions under which raw materials semi-finished products and finished products are stored and the quality and stability of finished products. This department has to establish shelf life and storage requirements on the basis of stability tests related to storage conditions and when necessary revise control procedures and specifications and finally examine returned products as to whether such products should be released, reprocessed or destroyed.

**Requirements of Plant and Equipment**

The requirement of space and equipment vary according to the nature of pharmaceutical product to be manufactured at the Unit. Therefore, different equipment requirements for manufacture of various categories of drugs and preparation like ointments, lotions, creams, syrups, pills, tablets, powders, gelatin capsules, surgical dressings, eye-ointments, eye-lotions, suppositories, inhalers and parenteral preparations are prescribed. It may be noted that these requirements do not include requirement of machinery, equipment and premises required for preparation of containers or closures for different categories of drugs. The licensing authority has the discretion to examine the suitability and adequacy of the machinery equipment and premises for the purpose, taking into account the requirements of the licensee. These requirements are subject to modifications at

44 *Id.* at para. 1.2.16.
46 See *id.*, Schedule M. Part II
the discretion of the licensing authority if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case. It may be further noted that the rules provide for the requirement of equipments and space for certain categories of drugs only. There are in addition, other categories of drugs such as basic drugs, pharmaceuticals, chemicals and aids, medicinal gases, empty gelatin capsules, mechanical contraceptives and new dosage forms which are not listed in the Schedule. The licensing authority, in respect of such drugs, has the discretion to examine the adequacy of the requirements by keeping in mind the nature and extent of the manufacturing operations involved and direct the manufacturer to carry out necessary modification in them and only after such modifications have been carried out by the manufacturer, he has to approve the manufacture of such drugs.

It is doubtful whether the drug manufacturers really adhere to these statutory regulations especially while testing for contamination and before introducing the drug into market. Testing for contamination for instance, involve two methods. The conventional chemical method tests only for expected quantity of chemical. Traces of contamination may go undetected. In the instrumentation method the composition of the drug is revealed. It was noticed that most companies are reluctant to install the instrumentation method since it involves not

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47 See id., Rule 76(4) and 76(4-A).
only huge investments in its installations but also requires highly paid, skilled and technically qualified man power.\footnote{See \textit{Indian Express}, May 26, 1998, at p.12.}

In addition to this, many pharmaceutical companies including multinationals palm off their manufacturing to smaller establishments in a loan licensing arrangement\footnote{A loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by other licensee. See Drugs and Cosmetics Rules, 1945, explanation to Rule 69-A of. \textit{Supra.} n.49.}. They resort to this arrangement, enticed by the lower labour charge involved, without ensuring whether the establishment in question is geared up to meet the quality standards. It was noticed that the standard of hygiene maintained at most small units is appalling.\footnote{\textit{Supra.} n.49.} It appears that the licensing authorities also relaxed the requirements, as they are authorised to do so, by keeping in view the small extent of manufacturing operations involved in such units.

Although authorities claim that hygienic condition in small units or large units are always maintained satisfactorily, there had been several instances to prove it to be wrong. Justice Lentn Commission which looked into the JJ Hospital glycerol tragedy in Mumbai, found that the glycerin was adulterated with diethylene glycole - a toxic chemical which converted the drug into industrial grade glycerin.\footnote{See \textit{supra.} n.2.
Apart from the manufacturing problems, there is another hidden danger namely side effects. The system of reporting adverse reactions is still in nascent stage in India. Though there is a duty on the manufacturer under the rules to report any information about adverse reactions of any drug to the licensing authority, it may not be effective in the absence of a duty on the doctors to report such reactions immediately. There is an Adverse Drug Monitoring Cell under the Drug Controller General of India to record adverse effects of drugs which occur in patients. However, as of today no doctor is legally bound to report any such observations because there is no law which makes it mandatory to do so.

**Misbranded, adulterated and spurious drugs**

The Act intends to protect consumers from misbranded, adulterated and spurious drugs.

**Misbranded drugs**

A drug is deemed to be misbranded in the following situations.

(a) if it is so coloured, coated, powdered or polished that damage is concealed, or it is made to appear of better or greater therapeutic value than it really is, or

(b) if it is not labelled in the prescribed manner, or

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52 See supra. n. 48.

53 Drugs and Cosmetics Act 1940, section 17.
(c) if its label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

It will be observed that misbranding relates to description of goods in a manner as to falsify the true nature or quality of the drug. Requirements for labelling and packing of drugs are contained in the rules. These provisions are comprehensive but some of them are inapplicable to medicines made up for ready treatment prescribed by a registered medical practitioner. However, the label must give information relating to name and address of the supplier, name of patient, quantity of medicine, serial number of prescription register and if the medicine is for external use, the words 'for external use' to be printed on the label.

If a product of one manufacturer is being described as the product of another, it amounts misbranding. The Allahabad High Court was of the opinion that the label found on the ampules made it a misbranded drug within the meaning of all the sub-sections of Section 17. These ampoules with the labels which were found on them purported to be the product of the New International Chemicals while actually they were manufactured by Andrew’s Chemicals, Culcutta. They thus purported to be the product of a place other than the place where they were manufactured.

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54 Drugs and Cosmetics Rules 1945. See Rules 96 and 97.
55 Id. at Rule 94.
56 Dharam Dea v. State A.I.R. 1958 All. 865 at 872.
57 It may be noted that a part of this section has been deleted and incorporated in Section 17 which defines spurious drug with the amendment to the Act in 1982.
really produced. The label used on the ampoules was false and misleading as regards the name of the manufacturer and it gave the name of a fictitious company as the manufacturer of ampoules. The word ‘fictitious’ means forged. It appears that before a person could be held responsible for selling a misbranded drug there must be a comparison between the impugned drug and genuine drug which it is alleged to have imitated and the labels upon the drug and their containers as well.\(^\text{58}\)

**Adulterated drug**

A drug is deemed to be adulterated\(^\text{59}\) in the following circumstances:

- (a) if it consists, in whole or in part of any filthy, putrid or decomposed substance;
- (b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health;
- (c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed;
- (e) if it contains any harmful or toxic substance which may render it injurious to health;

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58 Misbranding is a common hoax and anonymous variations of a known drug are very common. It is to the advantage of the consumers if he knows the names of the drugs he wishes to purchase especially in the case of home remedies that are sold and are available without a prescription. Here are a few samples of how a consumer can be cheated by mis-spelt variations of a popular drug.

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<tr>
<td>Analgin</td>
<td>Onalgin or Analagin</td>
<td>Amruthanjan</td>
<td>Amaranjan or Amarthanjan</td>
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<td>Crocin</td>
<td>Rocin</td>
<td>Codopyrin</td>
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<td>Iodese</td>
<td>Ioderex or Iodex or Iodin</td>
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<td>Saridon</td>
<td>Sardon or Saridan</td>
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59 Drugs and Cosmetics Act 1940. Section 17-A.
(f) if any substance has been mixed therewith so as to reduce its quality or strength.  

The essence of adulteration is mixing up of the drug with a foreign substance which renders it injurious to health or which may be a source of gain to the seller. State of mind of the person selling, or manufacturing is immaterial since liability under the Act is strict.

According to Chambers Twentieth Century Dictionary the word 'adulterate' means 'to debase, falsify by mixing with something inferior or spurious'. But, it will be appreciated that the framers of the Act could not feel contented with such definition alone because that would not serve the purpose. If the adulteration by itself was declared an offence the trade and commerce would probably come to an end for in that event products manufactured by combining various components would fall within the definition of the term adulteration. What the legislature intended to check and prevent was the adulteration of drugs which affected their purity. Accordingly, the legislature had to keep in its view different standards of purities in different varieties of drugs before attempting to define when and in what circumstances a drug shall be deemed to be adulterated. It was from this angle that a definition of the word 'adulteration' was given. But it may be noted that no general or all inclusive definition of the word adulteration could ever be put forth to achieve the desired effect except by laying down different standards of purities for different categories of drugs and by making the

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60 Ibid.
departure punishable. All these possibilities have been contemplated by the legislature and the Act covers a wide range of situations under which adulteration would be deemed to have been committed.

The different clauses of the section are not mutually exclusive. They may overlap one another and a drug may be found adulterated under one or more clauses. It will be a question of fact whether the ingredient contained in the drug is injurious to health or not. In determining whether an adulterant is 'injurious to health' under clause (b) of the Section, regard must be had not only to the probable effect of that drug on the health of the consumer but also to the probable cumulative effect of drug on the health of the person consuming such drug in ordinary quantities. In the same clause the word 'contaminate' was used. According to Oxford English Dictionary, the word 'contaminate' means 'to render impure by contact or mixture to corrupt, defile, pollute, infect'. Thus if a drug becomes contaminated or injurious to health on account of insanitary conditions in preparing, packing or keeping the drug it also amounts to adulteration.

Thus, a drug is deemed adulterated within the meaning of the Act if it consists of any filthy, putrid or decomposed substance or it is prepared, packed or stored under insanitary conditions thereby it may have been contaminated or rendered injurious to health. It is deemed adulterated if its content is composed of any poisonous or deteterious substance which may render the contents injurious to health. It can also be termed as adulterated if the colour additive is unsafe within
the meaning of the Act⁶¹. If the methods used in or the facilities or controls used for manufacture, processing, packing do not conform with good manufacturing practice to assure that the drug meets the quality and purity of characteristics which it purports to possess⁶². A drug is also deemed adulterated if it purports to be or represented as a drug the name of which is recognised in recognised pharmacopoeia⁶³ and if its strength differs from or its quality or purity falls below the standards setforth in it. And if it is a drug, the name of which is not found in any of the recognised pharmacopoeia, it is deemed to be adulterated if its strength differs from or purity or quality falls below that which it represent to possess. Again, a drug is deemed adulterated within the meaning of the statute if any substance has been mixed or packed with it so as to reduce its quality or strength or if any substance has been substituted for it.

SPURIOUS DRUG

A spurious drug is conceptually different from an ‘adulterated’ or ‘misbranded’ drug. A drug would be spurious if it is manufactured under a name which belongs to another drug, or is an imitation of or resembles some other drug to an extent that a buyer would be deceived, or if the label gives the name of a

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⁶¹ See supra n.16 for permitted colours for various categories of drugs.

⁶² See supra n.17.

⁶³ See Drugs and Cosmetics Act 1940, Second Schedule.
manufactures which is fictitious or does not exist.\textsuperscript{64} The essence of it is misleading the consumer into believing that a particular drug has been made or is the product of a manufacturer or a concern when in fact that is not true. Selling of spurious drugs is considered to be the most lucrative business in India due to weaken forcement of the laws.\textsuperscript{65} In the case of life saving drugs, if they are of spurious nature, there are serious consequences.

The purpose of this provision appears to be that no person should be entitled to misrepresent his goods as the goods of another person nor can any body use such mark, sign, symbol or device which can mislead a customer to purchase it. One should not also misrepresent the goods manufactured at one place as goods manufactured at different place.

The part of of the section emphasises upon the drug itself and the other part emphasises upon the label or container. The misbranding should be such that it cannot be detected by a lay purchaser with his ordinary deligence. It must be sufficient to make lay public and unwary purchasers to suppose that they are

\begin{quote}
\textsuperscript{64} \textit{Id.}, S. 17-B. reads : “for the purpose of this Chapter, a drug shall be deemed to be spurious, -
\begin{itemize}
\item[(a)] if it is manufactured under a name which belongs to another drug; or
\item[(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
\item[(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
\item[(d)] if it has been substituted wholly or in part by another drug or substance ; or
\item[(e)] if it purports to be the product of a manufacturer of whom it is not truely a product.”
\end{itemize}
\textsuperscript{65} D.N. Sharaf, \textit{Law of Consumer Protection in India}, N.M. Tripati Pvt. Ltd., 1990 at p. 188.
\end{quote}
purchasing the thing to which the resemblance relates. The standard of comparison is not that of the experts but of the lay public or the unwary purchasers and the resemblance need not be in all strict details but it must be sufficient to make unwary purchasers suppose that they are purchasing the thing the resemblance relates. The resemblance should be close to the drug misbranded so as to answer its trade description either in contents or get-up so as to give rise to the elements of deception practiced upon an average diligent purchaser. There should be reasonable probability of deception.

The complainant should establish that the drug was previously published and imitation is neither new nor original. The defendant will be allowed to go behind the certificate of registration to show that the proprietor is not the proprietor of the registered formulae in question. To disown imitation it may be proved that each principle or process of manufacture was previously well known to all persons engaged in the trade to which the drug relates. But what is necessary is to throw out the charge of imitation is that the mode of combining those processes was new and produce a beneficial result and that the specification claimed is not of the old process or any one of them but only the new combination. In such a case it will be established that the defendant had not derived his work

66 Modi Sugar Mills Ltd. v Tata Oil Mills Company Ltd., A.I.R. 1943 Lah 196.
from the plaintiff. It is a case of imitation of a mark, trade name or get-up with which the goods of another are associated in the minds of the public or of a particular class of public. The basis of passing off being a false representation by the defendant, it must be proved in each case as a fact that, the false representation was made. There is no such thing as monopoly or property of the 'nature of patent' in its use. Any body may use any name to designate his goods subject to the condition that he must not make directly or through the medium of another person, a false representation that his goods are the goods of another person. Where a mark or symbol by user in trade has secured for goods, it is a reputation which no body is entitled to imitate.

In the case of similarity of names, business should be so marked that the public is not deceived, business of one is not diverted to the other or no confusion is caused between the transaction of two companies. There should be reasonable precaution to clearly, plainly and conspicuously mark the articles. It is the false representation, lie and deception upon the ultimate consumer that creates liability upon the defendant.

In *Dharam Deo v. State*, the Allahabad High Court had decided apart from other things, the meaning of 'misbranding' of drugs. In this case the applicant, Dharam Deo Gupta was the Managing Director of a company known as

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69 A.I.R. 1958 All. 865.
The New International Chemicals Ltd., which had its depots at Lucknow as well as at Barabank. This company did not manufacture any drug, but it dealt with drugs. The Government of India invited tenders for the supply of one lakh fifty thousand ampoules of 10 c.c. equa pro injections. The necessary conditions and specifications were mentioned when these tenders were invited. One of the essential conditions was that the goods supplied should be 'own make' of the firm who submitted the tender. The applicant's firm, although it did not manufacture the required drug, submitted a tender and it was accepted by the Government.

As the applicant's firm could not manufacture this drug, they placed an order for its supply at Andrew's Chemicals (India)Ltd., Calcutta through some other firm by name Asha Medical Stores. Andrew's Chemicals (India) Ltd., supplied the ampoules to the proprietor of Ash Medical Stores. On the direction of the proprietor of Ash Medical Stores, the applicant took delivery of the ampoules and labelled them showing that the ampoules were purported to have been manufactured by New International Chemicals Ltd., Lucknow to which the applicant was managing director. The Director, Control Drugs Laboratory, Calcutta after testing the samples reported that oxidisable matter was above the British Pharmacopoeia limit and that the sample did not pass the pyrogen test and therefore, it was not of acceptable quality.
The question before the Court was among other things, whether the ampoules intended to be supplied by the applicant were misbranded or not. The court answered in the affirmative.

Another area where 'misbranding' of drugs appears to be rampant is the manufacturing and marketing of allopathic drugs in the name of herbal or ayurvedic drugs claiming that these are manufactured on the basis of ayurvedic principles or as advised in ayurvedic texts. Several Indian and multinational drug manufacturers are marketing formulations containing herbal or ayurvedic drugs. A few drug companies have even made this their exclusive business as it is easy to obtain a manufacturing licence for a drug labelled as ayurvedic or herbal. There is no barrier of scientific requirement worth the name. These licences are given by authorities liberally, without any verification of the claims, composition and toxicities because the licensing authorities have no means to do so.

The situation may appear to be identical for the licensing of allopathic drugs, but there is a difference. The composition of allopathic drugs can be tested in laboratories. This is not possible with herbal or ayurvedic drugs. The licensing authorities, the doctors and the consumers have to rely solely on the botanical names of plants mentioned on the label. Any unscrupulous business man may

70 Sec Drugs and Cosmetics Act 1940, Chapter IV-A and Part XXIII of Rules framed under it for provisions relating to Ayurvedic, Siddha and Unani drugs.

71 See Id., section 33 EEB for Regulation of manufacture for sale of Ayurvedic drugs.
mention names of several ingredients but may actually use only a few of them and
the consumer has no means of verifying the claim.

In order to encourage the use of herbal or ayurvedic medicines, the
government has as a policy to waive taxation on these products. This in turn has
helped to open the flood gates. Several Indian and multinational drug companies
have entered the market in a very big way, as there is a huge profit in these drugs.
The government has not imposed any price control over these drugs. Strangely,
through these products are granted licence as ayurvedic drugs or herbal drugs, they
are almost always propagated and promoted through the practitioners of allopathic
medicine.

There appears to be an erroneous belief existing among most of the
allopathic doctors and consumers that these drugs are free from toxicity and side­
effects because they are produced from natural substances whatever that means\textsuperscript{72}. The pharmaceutical companies have capitalised on these sentiments and reaped fortunes.

Since the practioners of modern medicine have hardly any knowledge about
these formulation, they accept whatever is told to them by the representatives of
drug companies without much questioning. Also, they hardly have any source of
from which to verify the claim and so the allopathic physicians take the claims in
their face value and go on prescribing the drugs. What is remarkable is that these

\textsuperscript{72} See K.B. Bala subrahmaniam, "Beware of the herbal drugs!" \textit{Indian Express}, April 2, 1991 at p.10.
products are hardly ever advertised and promoted to the practioners of ayurveda and other indigenous systems, who are the persons who are knowledgable about these preparations.

It seems, most of these drugs neither contain the ingredients used in ayurvedic formulation nor are they prepared according to the codified processes and methods mentioned in ayurveda. The drug manufacturers also do not bother to recommend methods of administration and diet restrictions as prescribed in ayurvedic texts. As regards the efficacy of these drugs, the manufacturers make wild claims without any scientific evidence whatsoever based on clinical trial or research.

There appears to be a painful misconception about the term 'natural' prevailing among the public and allopathic doctors. Natural means naturally occurring. When a substance is subjected to various processes, particularly chemical it can hardly remain natural thereafter. If by the term natural only the source is signified, many of the drugs of modern allopathic medicines are also natural. There are of course a number of allopathic synthetic drugs which are not produced out of air by magic. Their ultimate source is nature. In any case, one might ask, what is so holy about natural substances? Are we supposed to take poisons or harmful bacteria in the guise of ayurvedic or herbal medicines.

73 Ibid.
Ayurvedic drugs are called ayurvedic not because they are natural but because they are manufactured and administered on the basis of ayurvedic principles or as advised in ayurvedic texts. It is therefore unscientific and unethical on the part of allopathic doctors to prescribe these drugs. This amounts to quackery. Unless one knows and believes in ayurvedic medical principles and applies their precepts in diagnosis and treatment of patients, he has no medical, scientific, moral or ethical grounds to prescribe these medicines. This principle equally applies to the drug manufacturers and the government.

No one knows why the government is allowing the unscientific practice. It is the high time that the Union Health Ministry and the Drug Controller of India should think into the scandalous practice and enforce certain minimum requirements with regard to manufacture of herbal or indigenous drugs so that allopathic drugs or preparations do not pass on to the market in the name of herbal or natural drugs.

Prohibitions regarding imports, manufacture and sale

Section 10 of the Act prohibits import of any drug which is not of a standard quality, or is misbranded, adulterated or spurious or containing harmful ingredients. In addition, the Central Government has power to the prohibit by notifications any import of drugs which involve risks to human beings and animals or which do not have therapeutic value claimed for them.74

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74 Drugs and Cosmetics Act 1940. Section 10-A.
Under Section 18 of the Act the State Government by notification in the
official gazette may prohibit the manufacture for sale, distribution or stock or
selling of any drug which is not of a standard quality or is misbranded, adulterated
or spurious. The prohibition also extend to selling patent or proprietary medicines,
which do not contain labels giving list of active ingredients. Importing drugs in
contravention of section 10 and 10A, or manufacturing in contravention of any
provision of the Act and the Rules and more importantly, manufacturing for sale or
for distribution is also forbidden except under or in accordance with the conditions
of a licence issued for the purpose. The exceptions to the rule are, manufacturing
of a drug in small quantity for tests or such drugs not being of standard quality for
which permission has been granted

Powers and Responsibilities of Inspectors

Under the scheme of the Act, inspector is the key person for
enforcement of the provisions of the Act. The centre and state governments are
empowered to appoint inspectors. The qualifications of the inspector have been
prescribed under the Rules. Some of the important powers of an Inspector are as
follows:

(a) to inspect any premises where in any drug is manufactured, sold,
stocked, exhibited or offered for sale;

75 Id., proviso to S. 18(3).
76 Drugs and Cosmetics Rules, 1945, Rule 49.
(b) to take samples of any drug or cosmetic, and

(c) to enter into a premise, search any person, vehicle, vessel or conveyance at all reasonable times if he has reason to believe that the provisions of the Act has been contravened.

(d) to examine any record, report or document and seize the same if he has reason to believe that it may furnish evidence of any contravention.

(e) to order in writing not to dispose of any stock for a period not exceeding 20 days or to seize the stocks of such drugs.77

There are certain special duties for inspectors who are specially authorised to inspect the manufacturing premises. It is the duty of such inspector to inspect not less than twice a year, all premises licensed for manufacture of drugs within the area allotted to him and to satisfy himself that the conditions of licence and provisions of the Act and rules framed under it are being observed78. In the case of establishments licensed to manufacture products specified in Schedule C and C (1), it is his duty to inspect the plant and the process of manufacture, the means employed for standardising and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishments likely to affect the potency or purity of the product79. It is his duty to send a detailed report of the inspection.

77 Drugs and Cosmetics Act 1940, section 22.
78 Drugs and Cosmetics Rules, 1945, Rule 52 (1).
79 Id., Rule 52 (2).
to his superior officer immediately after the inspection indicating the conditions of the licence and provisions of the Act and Rules which are being observed and conditions and provisions, if any, which are not being observed. He can take samples of drugs manufactured on the premises and send them for test or analysis and institute prosecutions in respect of any breaches of the Act or Rules.

The inspectors may require any person to produce any record, register or document relating to the manufacture of any drug in respect of which he has reason to believe that there is a violation of the Act or rules. He can also exercise such other powers that may be necessary to discharge his duties effectively.\(^\text{80}\)

**Compulsory inspection before licence or renewal of licence**

An original licence granted for manufacture of drugs will be valid only for one year unless it is renewed. But if the application for renewal is made before its expiry, the licence would continue to be in force until orders are passed on the application.\(^\text{81}\) At the time of granting licence, the licensing authority can impose conditions which the licensee has to comply with during the manufacture of drugs. These conditions are generally relating to the safety measures that the manufacturer has to undertake and the premises, equipment and qualified staff that he is required to appoint and other measures provided in Schedule M and Schedule U and other provision of the Act and Rules.\(^\text{82}\)

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\(^{80}\) See Drugs and Cosmetics Act 1940, section 22 (cca) and (d).

\(^{81}\) Drugs and Cosmetics Rules 1945, Rule 77.

\(^{82}\) See *id.*, Rule 76, 76-A and 78.
Originally granting licence for manufacture of drugs specified in Schedule C and C(1) and X, it was made mandatory on the part of the licensing authority to inspect the establishment in which the manufacture is proposed to be conducted and examine all portions of the premises and plant and appliances, the process of manufacture intended to be employed and the means and the professional qualifications of the technical staff to be employed. With the amendment to these rules in 1992, it is mandatory to inspect not only before the licence is granted but also before granting renewal of every licence. This compulsory inspection is not just confined to the licences for the manufacture of drugs specified in Schedule C and C(1) but even to the licences for other drugs also. The inspector is authorised to conduct inspection with the assistance of an expert in the field. He should also examine and verify the statement made in the application in regard to their correctness and capacity with the requirements of competent technical staff manufacturing plants, testing equipments and Requirements of Good Manufacturing Practices.

The Inspector has to forward a detailed report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the provisions of law to the licensing authority.

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84 Ibid.

85 See id., Rule 80.
Thus, the duties entrusted to the inspectors are of wider range than mere inspection of retail shops. Such an inspector can search any premises including a dwelling house in order to detect any sale of drugs in contravention.\textsuperscript{86} It may be noted that the search and seizure under the Act by a drug inspector is equivalent to the search and seizure under the authority of a warrant under Section 98 of the Criminal Procedure Code. So it is not necessary for the inspector to record reasons for the search before making it.

**Procedure for taking samples**

In most cases it is necessary for an inspector to take samples of the drug. It is provided that the inspector shall tender the fair price for the samples taken and inform the person from whom it has been taken the purpose in writing for taking it. It is to be divided into four parts out of which one part is returned to the person from whom it is taken. Another part is sent to government analyst, third is to be produced before the court and fourth is to be supplied to the person from whom it had been acquired.\textsuperscript{87} Where the sample is taken from the manufacturing premises, it is sufficient to divide the sample into three portions only.

It is the duty of the government analyst\textsuperscript{88} to whom a sample has been sent for lest or analysis to furnish the report to the inspector in triplicate. On receipt of

\textsuperscript{86} Gyanendranath, Mittal v. Darmadas Bhatt, A.I.R. 1958 All. 163, at p. 164.

\textsuperscript{87} Drugs and Cosmetics Act 1940, section 23.

\textsuperscript{88} See id., section 3(c). Under this section a "Government Analyst" means an analyst appointed by the Central Government or State Government under Section 20.
the report the inspector delivers one copy of it to the person from whom the sample had been taken and another to the person, if any, specified in Section 18-A of the Act. The evidence contained in government analyst's report is conclusive unless the person from whom the sample was taken or person mentioned in Section 18A has within 28 days of the receipt of a copy of the report informed the Inspector or the court concerned that he intends to adduce against the content of the report. The court has been given power either on its own motion or at the request of the complainat or accused to cause the sample of the drug to be sent for test or analysis to the central laboratory. If this procedure is followed then the report of that laboratory is conclusive evidence of the facts stated therein. The inspector has the power to send a sample to the laboratory direct as well. The government analyst or the laboratory are under a duty to perform the protocol of tests as are mentioned in Pharmacopoeia of India or in other authoritative literature. If this is not done the evidence is not conclusive.

Burden of proof

When any drug is seized from any person in the reasonable belief that such drug is misbranded or adulterated, the burden of proving that such drug is not misbranded or adulterated shall be on the person from whose possession such drug

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89 Id., section 25(3).
90 Id., section 23(5).
was seized. This is contrary to the general principles of procedure. This might have been made keeping in view the difficulties of proving such action.

**Penalties for contravention**

The Act lays down penalties for contravention of provisions relating to manufacture, sale and distribution of drugs. The penalties for contravention are more stringent for drugs than for cosmetics and ayurvedic medicines. Under Section 27 a person is liable to be punished for not less than five years if he manufactures for sale or for distribution and sales or stocks or exhibits or offers for sale any drug deemed to be adulterated or spurious which is likely to cause death or grievous hurt, and in other cases be punished for not less than one year. Although courts have in several cases emphasised that a sentence in respect of offenders under the Act has to be deterrent, the fact remains that the enforcement of law leaves much to be desired.

Provision has been made for initiation of proceedings by the aggrieved person or by a registered consumer association. Further, any person or a registered consumer association is entitled to submit for test or analysis to a

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92 See Drugs and Cosmetics Act 1940, sections 27A and 31 I for penalties for contravention relating to manufacture, sale and distribution of cosmetics and Ayurvedic drugs respectively.


94 Drugs and Cosmetics Act 1940, section 32.
government analyst any drug purchased and to receive a report of the same. This is a salutary provision. Consumer organisations must make good of these benevolent provisions particularly against spurious and adulterated drugs sold to government departments or used in hospitals maintained by the state. However, for a consumer organisation to take up this matter, it is considered necessary to grant them on selective basis further powers and immunities as have been given to inspectors under the Act. Involvement of consumer agencies in the enforcement of the law is absolutely necessary in the light of the inadequate staff available for the enforcement machinery.

In addition to this problem, there is a preponderance of small scale industrial units in the country. This results in an increased workload for the drug control machinery in the States, which is inadequately manned in many states. There is also every need to see that these small units be guided by quality control procedures and good manufacturing practices.

95 Id., section. 26.
97 Critical shortage of Drug Inspectors has been highlighted recently. About 2700 inspectors are needed for the enforcement of the law whereas the actual strength is about 25 per cent of this number. There are 20,000 manufacturing Units and about 2,00,000 sales units in the Country. For details, see Rahul Pathak, "Drugs Controller says he is helpless, No Labs, no staff, no solution," Indian Express, Oct 18, 1989.
98 See V.C. Sane, "Drug Control : India". A Paper presented in World Congress on Law and Medicine, New Delhi, 1985.
Another serious constraint which drug control organisation at the centre and states appear to have been facing is the non-availability of well qualified and trained personnel. 99 Though such personnel is available in India, they are attracted to the industry where remuneration is attractive with opportunities for further advancement. It is necessary that government should adopt a policy which attracts personnel from Industry into drugs control organisation. This will lead to improvement in the technical capabilities of drugs control organisation in the country.

There are various reasons why there is little case law on the subject in India. The claim consciousness among consumer is very low, though financial and procedural obstacles are minimised to some extent by the establishment of consumer forums. Another difficulty stem from the peculiar nature of the product. It is often difficult to prove that one’s injuries are due to adverse drug reaction than they have been caused by other reasons. It is still harder to establish negligence. Experience of other countries suggest that a strict product liability approach do not make much difference. 100 Awareness that an injury was drug related or might have been drug related is often long delayed and it may be a

99 Ibid.
100 Harvey Jeff, "Regulation under Medicines Act 1968: A continuous prescription for Health," 47 Mod.L.Rev. 303 (1984) at p. 322. The author also quotes US law in this aspect. It seems in most of the US jurisdictions drug design defects have been treated as an exception to strict product liability and in effect, negligence must be proved. See infra text.
matter of years after the injury occurs. In such circumstances there is certainly an added temptation for less responsible manufacturers seeking quick profits.  

At the same time we can not quantify with precision the benefits of regulation in terms of safer, better quality and more effective drugs. If we take the estimated profits of this industry into account, the present cost of the regulatory requirements is much less. There is every need to strengthen enforcement machinery by allocating more resources. It is an acceptable price for a system to minimise risk of disasters such as thalidomide or J.J. hospital incidents.

**Drugs: product liability**

The above discussion reveal that a substantial protection is envisaged for pharmaceutical consumers. It relates to the quality and fitness of drugs manufactured for public consumption. The Act is designed to see that drugs are manufactured as per the standards stipulated in the Act and Rules. It prohibited misbranded, adulterated and spurious drugs from being manufactured for sale to consumers. To achieve the objective of protecting the consumer in all respects, it mainly relies on criminal sanctions. It is generally believed that when the consumer feels aggrieved, he often makes complaint to a public authority rather than to take legal proceedings. Of course, the Act provides for the aggrieved person or a recognised consumer association for taking samples to submit for test or analysis and receive reports of such test or analysis and also to institute

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prosecution\textsuperscript{102}. At the same time the Act do not the civil remedy for any injury suffered by the consumer due to the breach of statutory duty.

**Remedy under law of Contract**

Generally a seller who is sued under the provisions of the Sale of Goods Act is liable irrespective of due care and skill and the seller's strict liability extends to consequential loss caused by the defective drugs. It is not limited to the loss arising under the contract itself\textsuperscript{103}. Thus, if the buyer suffers personal injury through use of defective drugs, he can claim damages from the seller under the implied terms in the Sale of Goods Act despite the fact that the seller is not guilty of any negligence.

But the doctrine of privity of contract imposes serious limitations on this form of liability called product liability. Firstly, the buyer's remedy is only available against the actual seller. If the buyer wishes to sue the manufacturer, he cannot prima facie invoke the strict liability involved in a breach of warranty, but must still base his case on negligence\textsuperscript{104}. However, there are a number of qualifications to this prima facie situation. Strict liability can be effectively

\textsuperscript{102} Drugs and Cosmetic Act 1940, Section 26 and 32 as amended in 1986. It received the assent of the President on December 24, 1986 and published in the Gazette of India, Extra, Part II Section 1, dated 26th December, 1986, pp. 1-2.

\textsuperscript{103} See Chapter VIII of this work which deals with sales and distribution of drugs for detailed discussion on the liability of seller or distributor.

\textsuperscript{104} Tort liability for defective product was recognised in Donogue v. Stevenson, [1932] A.C. 562.
imposed on the manufacturer through third and even in fourth party proceedings. If
the buyer sues the seller for breach of warranty, the seller may claim an indemnity
from his own supplier, and that supplier if not himself the manufacturer may in turn
claim an indemnity from the manufacturer. As between each pair of parties, the
relationship will be contractual and liability for breach of warranty can be
established. For instance, in *Dodd v. Wilson*105, the plaintiff, a farmer, employed a
veterinary surgeon to inoculate his cattle with some serum. It proved to be
defective and many of the cattle died or became diseased. The plaintiff recovered
damages from the surgeon on an implied warranty. The surgeon brought in his
suppliers as third parties, and the suppliers brought in the manufacturers as fourth
parties. The surgeon obtained an indemnity from the third parties and they in turn
obtained an indemnity from the fourth parties. In this way the plaintiff effectively
obtained damages for breach of implied warranty from the manufacturer through
the intermediaries.

This is somewhat a clumsy and costly. Why should not the plaintiff have a
direct remedy against the manufacturer for breach of warranty? Moreover the
expedient may not always work, for example if one of the intermediaries is
insolvent or cannot be found or only carries on business overseas or has gone out
of business. A second possible expedient whereby a buyer may be able to hold a
manufacturer strictly liable despite the apparent absence of privity is the collateral

105 [1946] 2 All E.R. 691.
contract where an express assurance was given by the manufacturers directly to the consumer as in the case of Carill v. Carbolic Smoke Ball Co. But apart from this famous case, there are hardly any illustration of this possibility.

The collateral contract, however has serious limitations as a device for holding a manufacturer strictly liable for defective drugs. In particular it only helps a buyer where he can find some express statement or assurance that can be construed as a warranty. There is, as yet, no authority which goes so far as to hold that a manufacturer could be liable for breach of implied warranties on the basis of a collateral contract. A manufacturer market his products through retailers. He advertises directly to the public in respect of some products inviting them to buy. It does not seem unreasonable to hold that he is impliedly offering a warranty of reasonable fitness for ordinary use to a member of the public who buys the product.

The doctrine of privity of contract is also very material in the law of product liability in another major respect. Not only does the doctrine normally restrict liability to the seller but also confines the remedy to the buyer. A donee, a member of the buyer's family, an employee of the buyer none of these can sue the manufacturer for breach of warranty. This will leave the purchaser or user who is injured by a defective product to rely on a claim in tort for negligence.

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106 [1893] 1 Q.B. 256.
With the advent of consumerism, this privity doctrine is substantially altered. Many developed countries adopted legislation enabling a consumer to sue manufacturer directly\textsuperscript{107}. India also followed this in enacting Consumer Protection Act 1986\textsuperscript{108}.

**Remedy under the law of tort**

In *Donoghue v. Stevenson*\textsuperscript{109}, the House of Lords held that the manufacturers of defective product owed a duty of care in negligence to the ultimate consumer of the product, notwithstanding the absence of any contractual relationship between the consumer and the manufacturer. In the course of his speech Lord Atkin expressed the duty in these terms:

"A manufacturer of products which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care."\textsuperscript{110}

Another judge of the Court said that the defendant who brought himself into a direct relationship with the consumer by placing his product upon the market in a


\textsuperscript{108} For a discussion on the definition of consumer see Chapter I supra.

\textsuperscript{109} (1932) A.C. 562.

\textsuperscript{110} *Id.* at p. 599.
from which excluded any other intermediate examination was liable for the consumer. The manufacturer’s duty has been given a broader interpretation by including many products under the definition of ‘drugs’ and ‘consumer’.

An issue that arises in the context of pharmaceutical products is the possible liability of statutory regulatory agencies. Under the Act of 1940, the manufacture and distribution of medicines in this country is regulated by the licensing authorities of the state and Central Government. The Central Licence Approval Authority assesses manufacturing licence application and renewals and only when satisfied as to the requirements of safety, quality and efficacy, the licences are granted or renewed. The effect is that drugs which are released into the market are being manufactured according to the safety standards monitored by the statutory authority. In such circumstances, if the product is found to have been defective, it is arguable that the licensing authority should be responsible along with the manufacturer, for allowing a defective product to be marketed. The Act grants a general immunity on the authorities from any action arising out of the consequences of their decisions. By such provisions whether the state can skirt its responsibility to the public in granting licence. It has also been argued that the imposition of duty of care on the licensing authorities might lead to conflict of

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111 See Chapter 1 of this work for detailed discussion on the definition of ‘drug’ and ‘consumer’.

112 Drugs and Cosmetics Act 1940, Section 37.
duties, in which the regulatory agencies may adopt an unusually conservative or
defensive approach to its functions because of the fear of liability. This practice
may not be in the public interest\textsuperscript{113}. Even in a recent case decided in England, the
Court maintained restraint and said that "the Courts should proceed with great
cautions before holding liable in negligence those who have been charged by
Parliament with the task of protecting society from the wrong doings of others"\textsuperscript{114}.

It is difficult to predict whether, if the matter had to be decided in India, the
regulatory bodies established by the Drugs and Cosmetics Act, 1940 would be
held to owe a duty of care to individual patients in performing their statutory
functions of authorising and reviewing the licences of pharmaceutical units. But it
may be argued that in the light of \textit{A.S.Mittal v. State of U.P.}\textsuperscript{115} and \textit{Paschim
Banga Khet Mazdoor Samity v. State of West Bengal}\textsuperscript{116} does provide some
support to the proposition of state liability. It is submitted that the regulatory
agencies established under the Act 1940 is clearly directed to the protection of
members of the public from risks to their health. In principle, the regulatory
agencies should be held to owe a duty of care to individual patients who suffer
injury as a consequence of negligence in discharging their statutory duties.

\textsuperscript{113} Harvey Teff, "Regulation under Medical Act 1968: A Continuing Prescription for Health" 47 Mod.
L.Rev.303(1984) at pp.310-311
\textsuperscript{115} (1989) 3 S.C.C. 223
\textsuperscript{116} (1996) 4 S.C.C. 37.
The manufacturers have a duty to exercise reasonable care in the design of a new drug. It includes an obligation to be careful in conducting the research which goes into the design. One of the difficulties is that the defect may not have been apparent before the product is marketed. For liability in negligence the defect must have been foreseeable at the time of design and manufacture. If the risk was unforeseeable in the light of scientific and technical knowledge at the time of marketing, there is no negligence. But where there is a graver danger, the greater the need for special care and in some instances the risks may be so great or their elimination may be so difficult to ensure with reasonable certainty that the only reasonable course open to the manufacturer is to abandon the project altogether. The law requires even pioneers to be prudent.

The difficulty with medicinal products is that most of these drugs are recognised as carrying some degree of risk from side effects, allergic reactions, or other unforeseen consequences. The question of what is safe is inevitably a relative concept, particularly in this field. It is a question of fact whether a reasonable person would consider the relative risk acceptable given the objective desired in using the product, and the risk associated with alternative treatments or nontreatment. The risks that would be acceptable in producing analgesic would be far less than the risks attached to a new drug for the treatment of diseases like cancer or AIDS. Provided that the risk/benefit ratio is acceptable, and provided
the manufacturer has taken all the care to eliminate risks by proper scientific research, it is not negligent to market the drug.

An adequate warning may be sufficient to discharge the manufacturer's duty of care. It is not necessary that the warning be addressed directly to the consumer where the drug is intended to be purchased on prescription. Prescription drugs are available only on prescription and the prescribing doctor is in a position to take into account the propensities of the drug and the susceptibilities of the patient. In *Buchan v. Ortho Pharmaceuticals (Canada) Ltd.*\(^{117}\), Robins J. Commented that:

".....the manufacturer of drugs, like the manufacturer of other products has a duty to provide consumers with adequate warning of the potentially harmful side-effects that the manufacturer knows or has reason to know may be produced by the drug.....In the case of prescription drugs, the duty of manufacturers to warn consumers is discharged if the manufacturer provides prescribing physicians, rather than consumers, with adequate warning of the potential danger."\(^{118}\)


\(^{118}\) *Id.*, at para.8-033
In the absence of a mandatory duty on the manufacturers to supply data sheet to the prescribing doctors, this principle of exempting the manufacturers from liability is not satisfactory. Another question that may be pertinent here is, relating to adequacy of warnings. An adequate warning should be communicated clearly and understandably in a manner calculated to inform the user of the nature of risk and the extent of the danger. It should be in terms commensurate with the gravity of the potential hazard. To be effective, a warning must reach the consumer patient. The rational for this approach is that in the case of oral contraceptive pill there is greater participation of patients in the decision to use the drug. There may be substantial risks associated with its use. There is frequently limited participation by the physician in the decision to take the pill and there is a real possibility that patients may not be fully informed by their doctors. In such cases the principle of intermediary rule should not be made applicable to the manufacturers.

Where the alleged negligence consists of a failure to warn either the consumer or the doctor about the side-effects or contra-indications of a drug, the plaintiff still has to prove that had the warning been given he would not have taken the drug. In other words he must demonstrate that the negligent omission caused or contributed to the damage. In the case of prescription drugs, where the evidence is that adequate warnings would have had no effect on the decision of the
doctor prescribing the drug, the patients claim against manufacturers will fail on the ground of lack of causation\textsuperscript{119}.

If a danger becomes apparent subsequent to marketing the drug, it will be negligent on the part of the manufacturer to continue to produce the same unmodified product or at least to do so without attaching a warning. In addition, the manufacturer is under a continuing duty in respect of products already in circulation which are known to be defective. The manufacturer must take reasonable steps either to warn users of the danger or recall the defective drug.

But where a manufacturer has complied with the standards normally adopted within industry, this will usually be taken as good evidence that he acted with reasonable care, just as departure from common practice may be evidence of negligence. However, neither is necessarily conclusive of the issue. In the case of drugs, manufacturers must comply with statutory requirements of the law. Compliance will not be conclusive but it will be undoubtedly constitute strong evidence in support of the exercise of reasonable care.

The burden of proving negligence rests with the plaintiff. The effect of this is that in cases of manufacturing defects the plaintiff has to establish negligence by proving the existence of defect. It will be very difficult if the defect is in design. Where a product perform as it was designed and intended, there is no obvious standard to compare it. In addition to this the plaintiff has to prove that

\textsuperscript{119} Id., at para. 8-038
the defective product in fact caused the injury of which he complains. This will tend to be more difficult. There may be difficulty in isolating drug-induced harm from the background incidence of such injuries. Merely proving an increased risk of injury does not itself establish causation. The question is whether one can infer a casual link by taking a common sense approach to attributing cause. This problem would be multiplied in cases of prescription of a generic drug to identify the defendant among the multiple manufacturers of the same generic drug. It may be impossible for the plaintiff to say which manufacturer was responsible for the drug he took, especially if it was taken over a long period of time.

This issue was addressed by the Supreme Court of California and established a novel theory of liability with far reaching implications. In Sindel v. Abbott Laboratories, the issue concerned Diethylstilbestrol normally referred by generic name “DES”, a synthetic drug developed to prevent miscarriage. After an estimated three million women had taken it, adenocarcinoma, a rare but fatal form of cancer was found in a small number of daughters exposed to the drug in utero. There were as many as three hundred pharmaceutical companies which might have been producing the drug since it was never patented. Furthermore, adenocarcinoma manifests itself only after a minimum latency period of some ten or twelve years and often after twenty years or more. In the circumstances, vast

majority of plaintiffs were unable to identify the specific company which manufactured the pills taken by their mothers.

The plaintiffs argued before the Court to consider the two approaches to overcome the causative factors problem. One such approach was 'alternative liability' formula. Under the doctrine of alternative liability, where two or more defendants have committed acts of negligence in circumstances which make it impossible for the plaintiff to prove which of them caused him damage, the burden of proof shifts to the defendants to show that they were not responsible. In default of such proof, the defendants are held jointly and severally liable. But this solution has normally been adopted only where all potentially liable defendants have been joined in the action. In Sindell, only five out of two hundred or more potential defendants who had produced the drug were brought before the Court. Since this created a substantial possibility that none of them made DES which caused the injury, the court refused to apply the doctrine.\(^{121}\)

The plaintiff also sought to rely on another doctrine called 'industry-wide liability'. According to this theory, each manufacturer of a product could, in appropriate circumstances be held jointly and severally liable for all injuries caused by adherence to an industry-wide standard of safety. The Court held that there was delegation of safety functions to a trade association in drug industry.

\(^{121}\) It was however alleged by the plaintiff that some half a dozen companies produced 90 percent of DES marketed. See Harvey Jeff, "Market Share" liability-novel approach to causation", 31 ICom.L.Q. 840(1982) pp.841-844.
Moreover, the close regulation of the pharmaceutical industry by FDA means that standards followed by manufacturers are largely imposed by the Government, an additional reason for the reluctance of the Court to apply industry-wide liability doctrine in DES case.

Having examined and found wanting the various theories of liability put forward by the plaintiff, the Court proceeded to construct a novel theory of "market share" liability. It held that it was ".... reasonable....to measure the likelihood that any of the defendants supplied the product which allegedly injured plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose". The Court held that the principle applies only when the plaintiff joined in the action manufacturer of "substantial share" of the DES which her mother might have taken. Then the burden would shift to each company to show that it could not have made the particular substance which injured the plaintiff. In default of such showing, it would be liable for the proportion of the judgment represented by its share of the market.

The primary justification advanced for this bold departure from orthodox causation requirements was that "as between innocent plaintiff and negligent defendants, the latter should bear the cost of the injury" Just as product liability

122 See ibid.
123 Ibid.
which generally was seen as a means of overcoming defects in traditional common law negligence, market share liability is viewed as a practical solution to the problems created by harmful products which cannot be traced to any specific producer. Adoption of this “market share” liability principle will herald new horizons in product liability cases especially in pharmaceutical product cases inspite of some practical difficulties like what constitutes “substantial share” of the defendants in the market. It is a breaking point to the causation principle. One might speculate whether Indian legal system would adopt this principle especially in the context in which it has been showing its willingness to depart from strict traditional roles.

Therefore, the traditional tort system suffers from more defects in its application to drug injuries. There is vast literature with the writings of law reformers whose studies had convinced that there are severe short comings in the tort law. One claim is that the tort treatment is particularly unjust and is administratively too costly. It was alleged that the combined legal expenses for plaintiff and defendant as well as state’s expenses in terms of court’s time, the litigation consumed far exceeded the claimant’s compensation. Another problem is that tort solution requires unusually difficult determinations of causation as witnessed in cases like Sindell. Another problem with the tort of negligence is the

\[124\] Id. at p.842.

exclusion of 'development risks'. Perhaps it is the most important practical limitation on liability for negligence. Development risks are risks which the manufacturer neither know nor should have known at the time of marketing in the light of existing scientific knowledge. Even under strict liability there is strong support for excluding such risks which, it is feared, would expose the industry to an impossible burden. Other arguments against tort solutions are difficulties of access to evidence particularly in drug defects and possibilities of insolvency of wrong doer.

Perhaps, the experience of these difficulties in the drug related tort claims, special plans have been devised by some of the advanced countries to address the problem. In Germany, major insurers underwrite individual producer's strict liability at reasonable rates. These exclude non-pecuniary losses. They also limit the liability to amounts within the capacity of the insurance industry. By adhering to the principle of individual liability, it was backed by compulsory insurance on the part of the pharmaceutical industry. The scheme was intended only for personal injury and death resulting from defective drugs. It reaches also to non-negligent manufacturing defects and failures to warn. In Sweden a voluntary group insurance was set up jointly by the Pharmaceutical manufacturers and importers with the major insurance companies. This scheme covered all drug

127 Id. at p. 301.
related injuries including injuries due to subsequent change in the composition of a drug and injuries due to misdiagnosis and wrong prescription.

In Scandanavian Countries, these disputes are relegated to a drug injury committee. Compensation includes for pain and suffering, disfigurement and general inconvenience in accordance with prescribed tariffs but in the case of longer-lasting and severe disabillity, the compensation would be in the form of indexed periodical payments\textsuperscript{128}. In Japan, a legislative enacted special compensation fund with social security overtones was created. The entitlement is defined on a no-fault basis but the victims remain free to pursue their tort remedy. The fund is financed by manufacturers and importers of drug according to prescribed formula having regard to the number of drugs sold, their price, and their risk rate and finally by discretionary government subsidies.

Such special compensation plans are desired in India in the light of long run, heavy expensive, adversorial system of litigation and difficulties is proving causative factors in the adversary litigation of drug claims. Such plans are not new ideas to our system. Workers compensation and compensation plans for motor accidents etc. are already in vogue. There are also provisions in the Public Liability Insurance Act 1991 to compensate the victims from injuries caused due to handling of hazardous substances. The Act was mainly intended to compensate the victims of industrial hazards like Bhopal gas tragedy. Such intention is evident

\textsuperscript{128} Id. at p. 302.
when the Act defines hazardous substance\textsuperscript{129} to mean that which has been defined under Environmental Protection Act 1986. It may be submitted that these provisions can be extended to cover the injuries caused by hazardous drugs by a strained interpretation of the provisions. But it will be safe to have a separate compensation plan to cover the victims of pharmaceutical products.

\textsuperscript{129} Public Liability Insurance Act 1991., Section 2(d).