CENTRAL SECRETARIAT

REPORT

OF

THE PHARMACEUTICAL ENQUIRY COMMITTEE

MINISTRY OF COMMERCE & INDUSTRY

GOVERNMENT OF INDIA

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CHAPTER V

STANDARDISATION, CONTROL OF QUALITY AND ADMINISTRATION

(a) Present Methods adopted in Advanced Countries

1. General.

1.1. A study of the methods of standardisation and control of quality of drugs in advanced countries necessitates a brief consideration of "drug standard" in addition to a review of the machinery for enforcing legislation pertaining to drug standardisation and quality control. In this report, three countries have been selected for detailed consideration, *viz.*, the United Kingdom, the United States of America, and Canada, as these would suffice to give a thorough insight into the trends of modern drug legislation and the machinery for its enforcement.

2. United Kingdom.

2.1. The basic legislation pertaining to drugs in the U.K. had its origin in the Sale of Food and Drugs Act of 1875. The purpose of the 1875 Act was the one of making better provisions for "the sale of food and drugs in a pure and genuine condition." Three major offences against the consumer were enumerated:

(i) It was forbidden to mix, colour, stain or powder any food or drug with any ingredient which made that food or drug injurious to health or any drug with any ingredient so as to affect injuriously its quality or potency.

(ii) It was made an offence to sell, to the prejudice of a purchaser, any food or drug, not of the nature, substance and quality demanded. This section was by far the most important one in this enactment, and it was and still continues to be, the keystone of the enforcement sections.

(iii) It was an offence to use a misleading label or one which falsely described the food or drug.

2.2. In 1928, the Food and Drug Adulteration Act of 1928 was enacted. This Act was a comprehensive statute and brought together the spirit of all the various food and drug enactments since and including the Act of 1875. It did not contain any substantially new concepts of law relating to food and drugs. In 1938, the Food and Drugs Act of 1938 replaced the 1928 Act. This enactment was much more than a consolidating enactment, for it recognised for the first time, the necessity of authority to establish standards for foods and to deal with advertisements and labels. It took note of the potential force of labels and advertisements as a means of informing and influencing the consumer. The 1938 Act provided, that the label should

state explicitly the substance added or the constituent abstracted, and must be of adequate size, with the required information distinctly and legibly printed and conspicuously visible. The Act further prohibited the use of a label, falsely describing any food or drug, or otherwise calculated to mislead as to its nature, substance or quality. Likewise, it also prohibited the publication of an advertisement falsely describing any food or drug or otherwise calculated to mislead as to its nature, substance or quality. In addition to the substantial advance in the field of "misbranding" through more adequate control of labels and advertisements, the legislation contained provision for the first time to authorise the Minister of Health to make regulations prohibiting or restricting the addition of any substance to, and regulating generally the composition of food. This constituted the most revolutionary change in the law.

2.3. The actual execution and enforcement of the Act is the duty and responsibility not of a Central Government department, but of certain local authorities, known as "Food and Drug Authorities". For this purpose, the United Kingdom is divided into groups on a population basis, and these groups, be they County Councils, City Councils, or Borough Councils, act as Food and Drug Authorities for their areas. Each Food and Drugs Authority must appoint a Public Analyst, whose appointment requires the approval of the Minister of Food. There are over 200 Food and Drugs authorities and about 120 public analysts. Every public analyst is an independent expert, and is, therefore, in a position to report to his authority on any sample without regard to the views, which might be held by other public analysts. Sampling of food and drugs is carried out by sampling officers appointed by the Food and Drugs authorities.

2.4. One aspect, which is perhaps worthy of observation relates to the relative importance given in the Food and Drugs Act to *treatment of drugs*. The present Act and the preceding Acts purported to be drug Acts as well as food Acts. The original Act of 1875 dealt with the subject of Food and drugs in term of same equality, but the subsequent legislation practically ignored the subject of drugs and the present Act of 1938 is essentially a public health and food statute and is not in any sense a drug statute. Out of 103 Sections of the Act, a bare half a dozen include the word, "Drugs". Thus, in considering drug legislation in United Kingdom, it becomes essential to consider other enactments such as the Therapeutic Substances Act, the Medicines and Pharmacy Act, to mention only two. Further, it is a curious situation, that none of the English Statutes which deal with "Drugs" purport to establish an official standard for drugs, nor does the 1938 Act give the Minister of Health, power to establish standards for drugs, as it does in the case of foods. The British Pharmacopœia, which is a statutory publication, is only a presumptive standard in the United Kingdom.

2.5. The only drugs for which statutory standards exist are those covered by the Therapeutic Substances Act, 1925. In spite of the all-embracing title of this Act, the number of substances controlled is small. As has been explained above, quality control in the U.K. depends on the activities of public analyst and few, if any, of these

officials have the facilities or experience to carry out biological assays. The Act was, therefore, passed to create a means of controlling substances, of which the purity or potency cannot be adequately tested, by chemical means. It exercises a much closer type of control than the Food and Drugs Act. When the Act was first passed, the substances covered were vaccines, sera, toxins, anti-toxins and antigens, arsphenamine and "analogous substances used for the specific treatment of infective disease", insulin and injectable pituitary extract. Provision exists in the Act for bringing additional substances under its control by the issue of departmental regulations without prior reference to Parliament, and in addition to those listed above, the other "therapeutic substances" now are: Surgical ligatures and sutures; preparations of human blood; organic substances having the specific biological action of curare, and preparations the purity or potency of which cannot be adequately tested by chemical means; penicillin and its injectible preparations; Aureomycin and Streptomycin. The Act prohibits the manufacture for sale of any therapeutic substance, unless a licence is first obtained from the proper authority. The conditions, which must be complied with before a licence is issued, are set out in regulation. The licence, which has to be renewed every two years, is issued, only after the Ministry of Health is satisfied, on a report of an inspector, that the licensee's technical staff, premises and plant are adequate for manufacturing and testing purposes. The licensee must allow his premises to be inspected at any time; he must, if so required, supply samples of each batch to the Ministry and undertake not to issue any for sale until authorized to do so. Records must be kept of tests applied to each batch and copies must be supplied to the Ministry, when required. For each therapeutic substance, a non-proprietary name is specified, which must be printed on labels in letters not less conspicuous than those in which any proprietary name is printed. This non-proprietary name is termed in the Act a 'proper name', a somewhat curious designation which seems to imply that a trade-mark name is improper. In practice, the requirements is a satisfactory compromise between the interests of manufacturers, who can still advertise their brands of therapeutic substances, and the official views of organized medicines that brand names confuse the doctor and lead to irrational therapeutics. Labels must show the number of the licence under which the substance is made, the manufacturer's name and address, the potency, the expiry date, storage instructions, and certain other details of minor importance. The object, of course, is to ensure, that any particular container can be readily traced back to the manufacturers' records and the tests carried out on it checked up. Details for carrying out tests for sterility and for freedom from abnormal toxicity are specified in the general part of the regulations, while specific requirements applicable to the individual substances, including tests for purity and potency, are described in a schedule to the regulations. The Act also prohibits the import of therapeutic substances into the U.K. except under a licence and provided that the strength, quality and purity conform to the requirements of the regulations. A licence can be obtained to import for purposes of research a therapeutic substance, which does not so conform, and similar provision is made to enable a manufacturer to make solely for export a therapeutic substance not conforming to the official requirements, but in granting the licence regard must be "had to the nature of any

arrangements for regulating the manufacture and sale of the substance in operation in the country to which the substance is to be exported." The Inspectors appointed under the Act visit the different Laboratories to see that the manufacture is properly carried out. They buy samples for analysis and tests by a central laboratory—the National Institute for Medical Research.

2.6. Offences against the Act are punishable on the first occasion by a fine and on subsequent occasions by a fine or imprisonment, but so far as is known, prosecutions have never been brought. The power to revoke a licence is perhaps a more effective weapon; but in any event the manufacture of the substances concerned is in the hands of firms of repute, which are always ready to cooperate with the Ministry of Health in any reasonable way to achieve the objects of the Act and Regulations. In framing the various regulations, consultation with an advisory committee is required by the Act, the committee consisting of representatives of the Ministry of Health and the corresponding departments in Scotland and Northern Ireland, of the Medical Research Council, the General Medical Council, the British Medical Association, the Pharmaceutical Society and the Institute of Chemistry. It will be noted that the committee does not include any representative of the manufacturers. It is understood that, in practice, members of the committee are usually consulted by correspondence and the committee as such rarely or never meets.

2.7. Another important piece of drug legislation in the U.K. to which reference must be made is the Pharmacy and Medicines Act of 1941. It is the responsibility of the pharmaceutical Society to enforce this Act, which has the following three main purposes:—

(i) It makes it an offence for any one to take part in the publication of an advertisement for any article in terms calculated to lead to its use for the treatment of human beings for any of the following diseases: Bright's disease, cataract, diabetes, epilepsy or fits, glaucoma, locomotor ataxia, paralysis, tuberculosis.

(ii) It requires the disclosure on the label of details of the composition of "any article consisting of or comprising a substance recommended as a medicine," when the article is sold by retail.

(iii) It restricts the retail distribution of any such article as mentioned in the preceding paragraph to medical practitioners, dentists, "authorized sellers of poisons" (*i.e.*, retail pharmacies—*see* below) and, subject to conditions, persons who have served a regular apprenticeship to a pharmacist or to a body corporate, which is an authorised seller of poisons.

2.8. The control on antibiotics in the U.K. is rather stringent. The quality of penicillin and streptomycin is controlled through regulations issued under the Therapeutic Substances Act. Distribution of the two antibiotics is controlled under another misleadingly named Act, the Penicillin Act, 1947. Although originally relating

only to penicillin, the Act contains a clause by which "such other antimicrobial organic substances produced by living organisms, as may be prescribed by regulations" may be brought within its control. Up to the present time, the additional antibiotics, to which the Act has been applied, are streptomycin, chloramphenicol and aureomycin, these being the only antibiotics available commercially in the U.K. at the present time. Provision is made for the inclusion of synthetic antibiotics having chemical properties identical with those of substances coming within the above description. The Act applies to the antibiotics themselves and to preparations containing any proportion of any of the antibiotics as an ingredient. Substances controlled under the Act can be supplied only by doctors, dentists, veterinary surgeons or persons acting in accordance with the directions of one of these (for example, nurses) or by pharmacists and authorised sellers of poisons acting on a prescription signed and dated by one of them. Wholesale transactions and sales to doctors, hospitals, etc., are exempted from the restrictions. A prescription may be dispensed only once, unless it expressly directs, that it may be dispensed at specified intervals or a specified number of times; a mere general instruction on the prescription such as "may be repeated" must not be acted upon.

2.9. The law relating to sale of poisons, in general, and of narcotic drugs, in particular, involves a vast amount of detail. The administration and enforcement of the legislation relating to poisons is a responsibility of the Pharmaceutical Society, which operates in this respect through a number of inspectors. The routine enforcement of the narcotic drugs legislation is to some extent undertaken by local police officers, but in special cases, assistance of more experienced officers of the government department concerned is taken. The statutory law relating to poisons is the Pharmacy and Poisons Act which contains detailed provisions relating to manufacture, storage and sale of what are termed "listed poisons". The Act provides for the creation of a Poisons Board consisting of representatives of the Pharmaceutical Society, various government departments, various medical bodies and the Royal Institute of Chemistry. Its functions are to make recommendations to the Home Secretary regarding substances to be included in the "Poisons List" and the Rules to be applied to them. The legal requirements affecting the sale of poisons are contained in the Poisons Rules 1949, as amended. These prescribe among other things, details as to labelling of poisons. The legislation pertaining to narcotic drugs is the so-called Dangerous Drugs Acts, 1920 to 1932, and a relatively extensive series of regulations issued thereunder. The Acts deal with possession, sale, manufacture, import, etc., of opium prepared for smoking, crude drugs such as coca leaves, Indian hemp and raw opium and medicinal dangerous drugs, which have dangerous habit forming properties.

2.10. Thus it will be seen, that U.K. Drug Law is a mosaic of legislation, partly statutory but mainly delegated, enacted over a period of years, each piece of legislation dealing with a relatively specialised but restricted field, sometimes without much regard to the provisions of other Acts and Regulations. It is worthy of note, that there is no legislative control on imported drugs except those covered by the Therapeutic Substances Act, nor is there any piece

of legislation dealing with exports. Cosmetics are also not dealt with in any of the drug statutes. Lastly, there is no control, whatsoever, over the introduction of new drugs.

3. The United States of America.

3.1. The Food and Drug Administration until recently was a separate Bureau in the Federal Security Agency, but now it functions under the Department of Health, Education and Welfare. It is a separate government organisation employing scientific staff, inspectors, etc. The principal responsibility of the Administration is the enforcement of the Federal Food, Drug and Cosmetic Act. The headquarters organisation decides as to whether or not seizures, prosecutions and injunctions recommended by the field staff should be carried out. Its duties also include a wide variety of general supervisory administrative tasks, including such matters as budget, finance, personnel and new legislation. One of the most important functions is an advisory service through consultation and correspondence with manufacturers, who wish to get information about the application of the law to their products.

3.2. The Department is divided into the following thirteen divisions:—

(i) *The Division of Field Operations.*—This is directly responsible for supervision of the field force. It maintains the day-to-day contacts with the field organization and ensures that the acts are enforced uniformly throughout the United States. It prepares and conducts training programmes for the field force. It includes a total of eight professional people, all of whom have had extensive experience in the field either as chemists or inspectors. Quite naturally, the nature of their duties requires them to visit the various field offices at frequent intervals.

(ii) *The Division of Program Research.*—This is responsible for preparing programmes of operations covering each type and kind of commodity subject to regulation. It assembles statistical and other information concerning the various food, drug, and cosmetic industries, and considers the likelihood and evaluates the seriousness of violations. Based on this information, and after a study of the size of the industry in each of the field districts, it determines the approximate number of man-hours to be spent in investigations in each of these industries. Its planning is the keystone upon which are built plans designed to guarantee that all segments of a nation-wide industry will receive the same proportionate amount of regulatory attention.

(iii) *The Division of Regulatory Management.*—This is also staffed with technically trained people. Its task is to collect and assemble the factual evidence acquired in preparation for trial of contested cases. It directs the development of evidence cases designed to lead to precedent-establishing court contests to interpret the law. In the enforcement of the Food, Drug, and Cosmetic Act, complex scientific evidence is almost invariably required. Since the statute covers with a wide variety of different commodities, the factual evidence necessary for presentation in court covers the sciences of chemistry, pharmacology, bacteriology, medicine, veterinary medicine microscopy,

nutrition, and others. It is imperative that when the factual side of a lawsuit is presented, it be carefully expressed so as to be easily understood by attorneys, by juries, and judges. This office, of course, maintains a close relationship with the General Counsel's Office, and through it with the various United States attorneys throughout the country.

(iv) *The Division of State Co-operation.*—This has as its primary responsibility a close co-operation with state and local food and drug enforcement officials. They meet these officials frequently to prevent unnecessary duplication and bring about, as nearly as possible, uniformity of enforcement by the national and local food and drug officials. This office also has responsibility for making recommendations as to what foods should be standardized. In discharging this obligation, it works closely with local food and drug officials and with the field staff of the Food and Drug Administration.

(v) *The Division of Business Operations.*—This is concerned broadly with all phases of housekeeping. It prepares budgets, maintains fiscal records, and discharges various responsibilities concerning personnel. It also furnishes information to the public relating to the Food and Drug Administration.

3.2.1 The following eight technical divisions are responsible for advising the Food and Drug Administration as to the scientific facts within their provinces. Each of them determines the Administration's policy within its respective field. Laboratories are maintained, where research is conducted, which is designed to develop new or improved methods of analysis of foods, drugs or cosmetics. It is their responsibility to keep abreast of technical changes in the industries and to keep informed about scientific advances within their respective fields. In addition to the research, which they conduct, a number of them undertake examinations of individual samples, where the nature of the tests to be made is such that they cannot be carried out in the field laboratories.

(vi) *The Division of Medicine.*—This determines the medical policy of the Food and Drug Administration in such fields as the therapeutic value of drugs and devices. It determines the safety of these commodities and discharges a wide variety of responsibilities to implement the enforcement of the Act with respect to drugs and therapeutic devices.

(vii) *The Division of Food.*—This devises physical and chemical methods to determine the identity and quality and to detect adulteration of foods. It plays a large part in formulating the evidence to be presented by the government at food standards hearings.

(viii) *The Division of Microbiology.*—This is staffed with bacteriologists and microscopists. They develop the bacteriological and microanalytical methods for detecting filth and decomposition in foods and drugs. They have a large project dealing with food poisoning. They are leaders in many phases of sanitation control. One of their routine tasks is to test hundreds of samples of drugs intended for injection and of sutures used to close wounds after operations and to determine whether these are free from living bacteria.

(ix) *The Division of Antibiotics.*—Its principal responsibility is the certification of penicillin, streptomycin, aureomycin, chloramphenicol, and bacitracin. It conducts researches on new antibiotics and discharges a number of related responsibilities.

(x) *The Division of Cosmetics.*—This is responsible for the development of methods for the examination of cosmetics generally, and, in addition, maintains a laboratory where all coal-tar colours used in foods, drugs, or cosmetics are certified, before they can be legally employed.

(xi) *The Division of Pharmacology.*—This maintains one of the largest laboratories of this type in the world. Its duties involve the assay of certain drugs and glandular products by tests on animals. It determines the toxicity of ingredients of foods, drugs, and cosmetics. Each batch of insulin has to be certified by it before it can legally be sold.

(xii) *The Division of Nutrition.*—This develops methods of assay of vitamins and other ingredients pertaining to the nutritive quality of foods and drugs. As a routine, it conducts tests for vitamins and other nutritional factors by animal experiments.

(xiii) *The Division of Pharmaceutical Chemistry.*—This division has been formed recently. It was formerly a section of the Division of Medicine. The growing importance of the work, for which it is responsible caused it to be made into a separate division. The principal tasks assigned include the development of chemical and physical methods for testing drugs, and the routine analysis of many samples, which the field staff are not equipped to conduct. It tests, for example, the accuracy of clinical thermometers and the strength of surgical sutures. It serves as the Administration's adviser in the broad field of pharmaceutical chemistry.

3.3. For the purposes of enforcement of the laws charged to the Food and Drug Administration, the country is divided into sixteen field districts. Each of these district offices maintains a laboratory and an inspection staff. In addition to the district laboratories themselves, three other small laboratories were established in cities within the district territory. In 39 other cities one or more resident inspectors are assigned; they work under the direction of the district offices. Thus the Food and Drug Administration has offices in 58 cities scattered throughout the United States. Most of the approximately 60,000 samples of foods, drugs, cosmetics, and caustic poisons collected annually are examined in the 19 field laboratories.

3.4. *Food and Drugs Legislation.*—The laws pertaining to Foods and Drugs are both State and National in scope. Most of the States have their own separate laws. In several states, the laws follow the general principles of the Federal Act, but in some, there are material deviations. At present, the control of drugs is exercised by the Federal Food, Drugs and Cosmetic Act. It is designed to prevent the manufacture, sale or transportation of adulterated or misbranded or poisonous or deleterious drugs and medicines, among others, and for regulating traffic therein. The provisions of the Act apply to adulterated or misbranded drugs, which have been shipped or delivered for shipment in inter-State commerce, or which are exported or offered for export to foreign countries, or which are being transported

in inter-State commerce for sale or have been transported in inter-State commerce, or which have been received from a foreign country, or which are manufactured, sold or offered for sale in the district of Columbia, territories of the United States or insular possessions Each State has complete control over inter-State commerce and drugs produced within its limits.

3.5. The manufacture of adulterated or misbranded drugs in any territory or district of Columbia, the shipment of any adulterated or misbranded drug, out of or into, or the delivery of any such article in original unbroken packages in. any State, territory or district of Columbia or its sale in or export from the district of Columbia or the territories of the United States, is made punishable by the Act. Adulterated or misbranded articles in the course of transmission may be seized for confiscation by a process of libel for condemnation, and may be destroyed or sold or delivered to the owner, on his executing a bond to the effect, that they will not be disposed of contrary to the provisions of the Act.

3.6. The Act recognises the standards in the United States Pharmacopœia and the National Formulary as officially governing drugs or National Formulary. Drug is regarded as adulterated, if it differs from the accepted standard of strength, quality or purity and any other drug, if it falls below the professed standard of quality; but, in the former case. it will not be treated as adulterated, if the actual standard of strength, quality or purity be plainly stated on the container. Drugs recognized in the United States Pharmacopœia or National Formulary should be analysed by the tests laid down therein and other drugs should be analysed by methods prescribed by the Association of Official Agricultural Chemists or by methods satisfactory to the Food, Drug and Cosmetic Administration. 'Misbranding' takes place if the label of a drug contains a statement, design or device regarding the drug, or its ingredients, or of their curative or therapeutic effect which is false or misleading. Imitation of, or sale under the name of, another article, or the substitution of the contents of a package with other material, or the failure to bear on the label a statement of the quantity, or proportion of specified ingredients such as alcohol, etc., would also amount to misbranding.

3.7. No special supervising control is exercised over patent or proprietary medicines except as regards misbranding. It is expressly mentioned in the regulations that statement of the formula is not required on the label except in so far as it may be necessary to secure freedom from adulteration or misbranding.

3.8. The Act embodies special procedure for dealing with imports. The enforcement of the provisions relating to imported drugs is under the local direction of the officers of the stations of Food and Drug Administration. Collectors of Customs act as administrative officers in carrying out directions relative to the detention, exportation and destruction of merchandise and action under bond in case of non-compliance with the provisions of the Act. Merchandise will not be delivered to the consignee prior to report on examination, unless a bond for the value of the goods is given. If violation of the Act is disclosed, a formal enquiry will be held after notice to the importer. If goods are to be refused entry, the Chief of the Station will notify

the Collector of it, who will call on the importer to export or destroy them in three months. The goods may be released in certain cases after relabelling or compliance with stipulated conditions under the supervision of the Inspector. The Importer is required to pay to the Administration for the services of the Inspector, which are charged on the basis of time spent. If the goods are not "conditioned" within the period allowed, they will be exported or destroyed. The Collector will report the final action taken to the Chief of the Station.

3.9. An article of drug intended for export is not adulterated or misbranded within the meaning of the Act, if it is established by the shipper or exporter that the article is prepared, or packed according to the specifications, or directions of the foreign purchaser, and that no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which the article is intended to be shipped. Such an article should be labelled so as to show that it is intended for export and is prepared, or packed in accordance with the specifications or directions of the foreign purchaser. If, however, it is sold or offered for sale for domestic consumption, it will be subject to the provisions of the Act regarding domestic sale. The Regulations permit the import of adulterated foods or drugs for technical or restricted use under certain conditions.

4. Canada:

4.1. The Act in force in Canada is the Food and Drugs Act. It defines 'adulteration' and 'misbranding' of foods and drugs on the line of similar Acts in other countries. Every drug is to be deemed to be adulterated if its strength, quality or purity falls below the professed standard under which it is sold or if, when exposed or offered for sale under a name recognized in the latest edition of the British Pharmacopoeia or of any foreign pharmacopoeia or in some generally recognized standard work on materia medica or drugs, it differs from the standard in strength, quality or purity specified therein. The British Pharmacopoeia and the standards therein are specially recognized and, in the absence of any indication to the contrary, they govern every drug.

4.2. Any person, who by himself or his agent manufactures for sale, or sells any adulterated or misbranded article of food or drug, is guilty of an offence under the Act. Labelling as to 'purity' is prohibited, so also any misleading statements. The Act regulates the distribution of samples.

4.3. The Council of any city, town or other municipality may appoint inspectors. The Governor in Council has the power to make regulations, prescribing the duties of Inspectors and for designating as Government Analyst any member of the technical staff already appointed to the services of the Department of Health. The Inspectors are empowered to inspect and procure samples from manufacturers or vendors or from consignments sought to be imported into Canada and submit them for analysis by the Government Analyst. Any person can also submit samples to the Government Analyst for analysis. The Government may initiate prosecution in the case of

adulteration or misbranding. The Analyst should give a certificate as to the adulteration, and its injurious character; and it is open to the aggrieved party to contest it before the Chief Government Analyst, who may cause it to be re-analysed. The certificate of the Chief Government Analyst is final and conclusive. Proof, that the article was a bonafide purchase in the same state, as that in which it was sold, and that the vendor, with reasonable diligence, could not know of adulteration or misbranding, is a good defence. Either, he or the prosecutor, may in such a case, lay information against the third party, from whom the purchase was first made and the court can decide on the merits of the case.

4.3.1. Articles of drug, which are reported as adulterated or misbranded by the Government Analyst, may be seized and forfeited. Materials used for purposes of adulteration may also be seized, analysed and treated similarly.

4.4. The Canadian Act authorises the Governor in Council to adopt regulations prescribing standards of quality for any drug, to prescribe packaging or labelling, to prevent deception as to the character, strength, quality or quantity of any drug, to prohibit or restrict ingredients, which may be injurious to health to define the conditions of sale of any drug, and to avoid false, exaggerated, or misleading claims. The Act has appended to it two Schedules 'A' and 'B'; the first enumerates specific conditions, for which no drug may be recommended or sold to the general public, and the second provides a list of drugs, for which special regulations are deemed necessary.

4.4.1. A list of disease conditions for which no drug may be recommended or sold to the general public is published by Government (Schedule 'A') which is revised from time to time. The diseases listed in them include cancer, diabetes, tuberculosis, venereal diseases, and disorders of the menstrual flow. The purpose of this schedule is to obviate the necessity for proving that the claims are false, and more effectively, to discourage exploitation of the public through the sale of articles for diseases that cannot be treated safely and effectively through self-medication.

4.4.2. Special regulations respecting several classes of drugs described in Schedule 'B' have been provided for. This schedule is revised from time to time, by adding new classes of drugs or by deleting some of them. Schedule 'B' is divided into five parts according to the nature of the drug and the type of control deemed necessary. Part I includes hormones; Part II includes drugs that purport to be sterile and are intended for parenteral use; Part III includes drugs derived from micro-organisms like antibiotics, and biologicals and analogous preparations; Part IV includes organic compounds of arsenic, and analogous products for parenteral use; and Part V consists of 50 specified drugs. Standards of quality and potency prescribed for these drugs by the Canadian Government, take precedence over the standards laid down in the British Pharmacopoeia. If the Administrator considers tests and methods of assay prescribed in an official compendium insufficient, he may, after calling attention of the revision body to the insufficiency and allowing a reasonable time for revision, prescribe tests and methods of assay. The Schedule B drugs in Part II (sterile drugs for parenteral use) and in Part III

(antibiotics, viruses, among others) are subject to stringent licensing control of manufacturers. The licence is an annual one. It is issued after inspection of the plant, study of the qualifications of personnel, and study of the principles of manufacture and the equipment employed. It is conditioned upon the licensee's maintaining the premises under the direct control of a responsible qualified person and keeping satisfactory records of manufacture, testing, and distribution.

4.5. The manufacturer's right to keep off the label of proprietary and patent medicines, the formula or list of medical ingredients, has been conceded, at the same time control has been established to protect the public by licensing. The Proprietary or Patent Medicine Act, administered by the Minister of Health and Welfare, establishes the special controls. Proprietary or patent medicine is defined as an artificial remedy or prescription manufactured for the internal or external use of man, the name, composition or definition of which is not to be found in official pharmacopoeias, or upon which the true formula or list of medicinal ingredients is not conspicuously placed. A drug is considered a patent medicine only, if the ingredients thereof are not listed. The Canadian Act seems to give a manufacturer the choice of listing the ingredients and coming under the Canadian Food and Drugs Act or omitting such listing and being governed by the terms of the Proprietary or Patent Medicine Act. Under the Act, the manufacturer of a proprietary or patent medicine must register his formula and statement of uses with the Minister before offering the drug for sale. No claim can be made that the medicine will cure a disease. False and exaggerated claims are prohibited. The application for registration must state the type, and quantity of certain dangerous drugs contained in the medicine. Some narcotic and dangerous drugs are prohibited in patent medicines. The Minister may require that manufacture be continually supervised by a chemist or pharmacist. Upon registering, the manufacturer is given a registration number, which must appear in the labelling of the article. An annual licence to sell the medicine without disclosure of the formula is issued and it may be revoked for a sufficient cause. Presumably, revocation could be based upon the use of false or exaggerated claims. No proprietary or patent medicine can be sold from door-to-door, in public places, or high-ways, or through the mails. Failure to register the drug subjects it to seizure and the manufacturer to prosecution.

4.6. The Canadian Act authorises the Governor in Council to promulgate regulations defining the conditions of sale of any drug. Under this authority, a group of drugs has been limited to sale on the individual prescription of a physician. This is done by establishing a list of drugs that may be sold only on prescription. Articles are listed in general terms, for example, barbituric acid and any salt, homologue, or derivative thereof. The allowable claims that may be made for vitamins are established by regulations. These regulations are, incidentally, a result of cooperation between government and industry. The regulations prohibit entirely the use of testimonials on the label or in advertising. They prohibit any assurances to the general public regarding results that could be obtained from treatment by vitamin medication or from the addition of vitamins to the diet. Vitamin products sold to the general public must

contain an optimum minimum daily requirements and should not contain more than a specified maximum. Vitamin products containing more than the maximum are regarded as drugs for therapeutic use only and may not be advertised to the general public. The only general claims, which may be made to the public based upon the vitamin content of a food, dietary supplement, or drug, are the following:

(i) that vitamins are necessary for the normal functioning of the body;

(ii) that they aid in growth;

(iii) that they may help to maintain appetite; and

(iv) that they may help to maintain normal resistance of the body to infection.

The regulations also provide that certain specific claims may be made for each vitamin. They appear to be specially well-suited to the protection of the public, because of the many speculative and enthusiastic claims, that have been made by various investigators, as to the value of the vitamins in the prevention and treatment of illnesses. Some theoretical basis can be found in the scientific or pseudoscientific literature for almost any claim of curative value for almost any of the vitamins. The Canadian authorities appear to have allowed only those claims that have been justified by sound investigational work.

(b) Control over quality of Pharmaceuticals in India

1. Position till 1930.

1.1. India was largely dependent on foreign imports for drugs of modern medicine until after the First World War. The chief countries, from which these imports were received at that time, were Germany, France and Great Britain. As a result of the chaos, that followed the First World War, there was a mushroom growth particularly on the Continent of Europe of unethical drug manufacturers, who began to trade in faked and adulterated drugs with the East. This was particularly felt, as there was practically no Indian manufacturing industry to cater to the needs and requirements of modern medical practice. During the years from 1919—26, the Indian market became flooded with adulterated, substandard and faked drugs; and as no properly established organisation to control and check this menace existed, spurious and substandard drugs were sold openly at prices, which bore no resemblance to those of genuine products. Added to this, the medicines which were made available to the public, did not contain the required dosage. This state of affairs naturally had its repercussions on modern medical practice and the public. Protests arose from these quarters, which created a strong public opinion against the fraud, that was being perpetrated on the unwary and sick public, by sale in the open market of counterfeit drugs and adulterated and substandard medicines. Attention was also focussed on it by scientific journals, press and public propaganda.

1.2. In 1927, the late Sir Henry Gidney, a member of the Legislative Assembly, drew the attention of the House to what he described as the "Quinine Fraud", in which he produced definite evidence before the Assembly to prove that quinine tablets that were sold to the public contained either no quinine at all or were mostly chalk containing traces of quinine. He asked the Government to take steps to stop the existing evil of wide-spread adulteration of drugs in the country. In the years following, this evil was again forcibly brought before the Council of State by the Hon'ble Sir Haroon Jaffer, who moved a Resolution, recommending to the Governor General in Council to take immediate measures to control the trade in drugs and medicines by legislation, with a view to regulate their standardization, manufacture and sale. He characterised the then existing state of affairs as a great menace to public health and pressed for efficient safeguards to ensure the authenticity of medicines offered to the public. The commercial community also testified to the gravity of the situation. Genuine products could not find market due to the low prices at which faked substitutes were offered for sale, which affected the pharmaceutical industry to a great extent.

2. Drugs Enquiry Committee:

2.1. As a result of these protests, the Government of India in the late Department of Education, Health and Lands, appointed a Drugs Enquiry Committee in 1930, under the Chairmanship of Colonel R. N. Chopra, to go into the question of adulterated and sub-standard drugs sold in the country, both imported and indigenously manufactured, and to recommend steps by which this menace could be controlled and ethical drug trade established in India. This step marked the beginning of Drug Control in this country. The Drugs Enquiry Committee carried out a thorough examination of the problem, in all its aspects, and submitted a report in 1931.

2.2. They classified the drugs manufactured or sold in the country under the following broad categories :

(1) Indigenous crude drugs.
(2) Drugs of indigenous manufacture :—
  (a) Non-biologicals.
  (b) Biologicals.
(3) Imported drugs.
(4) Drugs for export.
(5) Patent and proprietary medicines.

The important general findings of that Committee in respect of quality are summarised below:—

> "The Committee has considered the problem in all its aspects, and feels convinced that it is justified in coming to the conclusion that the drugs in the Indian market are not above reproach and that many of them are of impure quality and defective strength. The evidence points to the conclusion that the traffic in such drugs is extensive and indiscriminate and that the strong language used by

some of the witnesses in characterising the situation is by no means undeserved or exaggerated. It is not possible to estimate the exact extent with greater precision."

"The evidence left no room for doubt that, in regard to adulteration, deterioration or tampering with the quality or strength of drugs, very little distinction can be made between imported and locally manufactured medicinal preparations. Even some of the preparations of the Government Medical Store Depots were called into question by some of the witnesses."

2.2.1. With regard to biological products, it was reported that even imported preparations, manufactured by reliable firms, having an established reputation and employing a competent staff of biochemists and bacteriologists, were sometimes found to be not upto standard. For instance, a number of sera, imported into this country, had strength much below the titre mentioned on the label. Many vaccines were also found to have deteriorated considerably. Certain gland extracts and preparations were defective and faulty, showing considerable variation in their activity and, in some cases, were quite inert. Insulin prepared by reliable firms, was found absolutely useless. The following extract from the Report explains the causes :—

"The variations in the activity of such products imported into India may be due to several reasons. Firstly, the drug may not be up to the prescribed standard. Owing to the unprotected condition of the Indian market, the facilities and the temptations for the sale of all kinds of inferior and deteriorated products are many and irresistible. Some of the importers do not hesitate to descend to the vile practice of getting hold of time-expired biological products from the European market, and importing them into India and selling them to dealers at a very cheap rate. Secondly, the products when sent out by the manufacturers may be perfectly sound and up to the standard, but may lose their activity during transit or storage."

2.2.2. With regard to biologicals manufactured in this country, there appeared to be general satisfaction as regards quality of vaccines and sera, though, it was noted that these were produced on a very small scale. The position in regard to organo-metallic compounds of Arsenic and Antimony—many of which were very potent —was far from satisfactory. These could be manufactured by anyone and put on the market without properly testing their strength or determining their toxicity.

2.3. As regards imported drugs, considerable emphasis was laid in the report on the fact that many foreign firms, which exported drugs to India, manufactured them specially for India, and exported drugs of a quality that were condemned by the authorities for their home consumption. It was noted that, whereas foreign Governments protected their own people by special Drugs Act, the same Governments allowed firms to export drugs to India without any State control.

2.4. The position of "crude indigenous drugs" and "drugs for export" at the time of Chopra Committee report may be taken together, as the former constituted the bulk of drugs for export. There was no control, whatsoever, on the cultivation, collection, storage, sale and export of drugs with the result that their potency and therapeutic activity were always a matter of conjecture.

2.5. The following main recommendations were made by the Committee: —

(i) Enactment of a comprehensive all-India legislation for the control of drugs an . Pharmacy either as a combined Act or a separate Drugs Act and a Pharmacy Act.

(ii) The setting up of an adequate machinery for control, inspection and testing of drugs to ensure uniformity of proper standards of purity and strength. Among other things, the Committee suggested that a well-equipped Central Drugs Laboratory with competent staff (Experts of various branches of drug standardization) should be set up at the Centre and similar laboratories should be set up in the Provinces to work in close liaison with the Central Drugs Laboratory; and

(iii) The setting up of a Central Pharmacy Council and State Pharmacy Councils with Registration Tribunals etc., for controlling, training, registration, etc., of pharmacists.

3. Drugs Act, 1940:

3.1. For a variety of reasons, the Government of India could not give effect to the scheme outlined by the Chopra Committee until January, 1937 when the Biochemical Standardization Laboratory was established in Calcutta, as a first step towards a more elaborate organisation for testing of drugs. This laboratory was set up to serve as a nucleus for the future Central Drugs Laboratory envisaged in the Chopra Committee Report. About the same time, legislation for the control of Drugs was in a drafting stage. In the meanwhile changes in the legal and administrative policy of the Central Government took place, as a result of the enactment of the Government of India Act of 1935, the subject "drugs" became a Provincial responsibility, the Centre being responsible only for imports. As a result a "Drug Import Bill" was prepared and placed for consideration before the Assembly in 1939. This, however, did not find favour with the public and all the Provinces clamoured for a uniform and comprehensive Legislation. This led to the introduction in 1940, of the Indian Drugs Bill in the Central Legislature. It was passed and received the assent of the Governor General in Council the same year and became the Drugs Act, in 1940. By this time the Second World War was in full swing, and India's commitment to War, both in personnel and resources, became more and more pronounced. It was not possible during this critical phase to implement this legislation of a longterm character in the country, and the implementation of the Act was delayed.

3.2. The main features of the Drugs Act, 1940 are:—

Functions of the Central Government:

(i) Constitution of a Statutory Board, called "The Drugs Technical Advisory Board" to advise the Central and the Provincial Governments (now State Governments) in technical matters relating to the Act.

(ii) Establishment of Central Drugs Laboratory.

(iii) Constitution of a Drugs Consultative Committee consisting of two representatives of the Central Government and one each of the State Governments, to advise all the Provincial Governments (now State Governments) in matters tending to bring about uniformity in the administration of the Act.

(iv) To control standards of imported drugs and to make rules in consultation with the Board for regulating the import.

(v) Establishment of adequate machinery for administration.

Functions of the State Governments:

(i) To control manufacture, sale, and distribution of drugs by the establishment of an adequate machinery consisting of licensing authorities, Inspectors and Government Analysts.

(ii) Establishment of State Drug Control Laboratories.

(iii) To make rules in consultation with the Drugs Technical Advisory Board for giving effect to the above.

3.3. The Central Government established the Drugs Technical Advisory Board in 1942 and drafted Rules to give effect to the Drugs Act, 1940 covering all aspects of the Legislation. These Rules were published for comments from the public as well as those interested in the manufacture, sale, distribution and import of drugs into India and also the Provincial (now State) Governments. All the comments received were examined by the Drugs Technical Advisory Board in 1945, and the final Drugs Rules as recommended by the Board were adopted by the Central Government in the year 1945 as "Drugs Rules, 1945". In order to secure uniformity, the Central Government Drugs Rules were adopted by the Provincial Governments as far as they were concerned.

3.3.1. The Biochemical Standardization Laboratory, established in 1937, was developed and eventually converted into the Central Drugs Laboratory in 1947 for carrying out the following main functions:—

(i) To test samples of imported drugs sent to it from ports;

(ii) To grant certificates of registration in respect of patent or proprietary medicines, which do not have their composition disclosed on the label. A Patent or proprietary medicine is one, which is a prescription or a remedy and not included in the official Pharmacopoeias or which is not recognised by the permanent Commission on Biological Standardization of the World Health Organisation;

(iii) To test samples of drugs referred to it by courts of Law in disputed cases. The report of this laboratory is taken to be final and as such, this laboratory functions as an appellate body in respect of drug standards; and

(iv) Any other function assigned to it by the Government.

The function of the Central Drugs Laboratory in respect of certain drugs such as sera, vaccine, toxins etc. has been assigned to the Central Research Institute, Kasauli.

3.4. In order to implement the Legislation uniformly Conferences of Provincial Representatives were convened twice in the year 1945-46 by the then Health Department, Government of India, where preliminary problems concerning the implementation of the Legislation were discussed. A Drugs Consultative Committee was established in 1948.

3.5. In order to regulate imports the Central Government established organisations at the Centre and at the ports of Bombay, Madras and Calcutta during 1946-48 and very recently one in Cochin, the above sea-ports having been notified by the Central Government as points of entry for the import of drugs. Drugs can only be imported at these points by sea and certain other specified air ports and land frontiers. At the Centre, in the Directorate General of Health Services the Government of India has appointed a Drugs Controller (India) who is also the licensing authority and is assisted by two officers, an Advisory Chemist and an Assistant Drugs Controller (India). At each of the ports of Bombay, Madras, Calcutta and Cochin an Assistant Drugs Controller has been appointed whose functions are (i) to control the quality of drugs; (ii) to ensure that the labelling and other provisions of the Drugs Act are followed by importers and (iii) to ensure that the importers of drugs requiring licenses possess the requisite storage facilities and take samples periodically or as often as they consider necessary and send them to a prescribed laboratory for test and report. These Assistant Drugs Controllers work in close liaison with the Customs authorities. The drugs which are found to be substandard are re-exported to the country of origin, if the defects cannot be remedied, or, alternatively destroyed. These officers have also been empowered to inspect periodically the premises, where imported drugs are stored and take samples therefrom to ensure that they have maintained their potency and strength. Batches of drugs, which are found to have lost their potency, are forced to be withdrawn from the market. The Assistant Drugs Controllers also advise the Customs Collectors, as well as the importers, on the provisions of the Legislation and the necessity for maintaining storage facilities for drugs imported.

3.6. *Control over Manufacture, Sale, and Distribution.*—Control on manufacture, sale and distribution of drugs is the responsibility of the State Governments. In all the Part A States and some of the Part C States, the Drugs Act has been enforced and a Drug Control Administration maintained for this purpose. But in most of the Part B States steps have yet to be taken to exercise this control. Sub-standard, adulterated and spurious drugs manufactured in States, where the control is yet to be exercised, often find their way into the States, in which the control is enforced and nullify its effects. Even in the States, where the Drug Control is in operation, it is not uniformly and effectively enforced. The Committee noticed during its visits that except in one or two States, the Drug Control Administration had been relegated to the background and was being treated as unimportant. The duties of the State Drugs Controller had been assigned to the existing Administrative Medical Officers like the Surgeon General or the Director of Health Services, who are already fully engaged with their duties and cannot be expected to spare sufficient time for this important work of drug control. In one of the States, this officer was also the Inspector General of Prisons. In making such appointments, the authorities concerned do not appear to have given due consideration to the scope, importance, technical nature and the type of work involved in the office of the Drugs Controller. To do justice to the work and be able to carry on the duties entrusted to them satisfactorily, the Drug Controllers both at the Centre and the States should be full-time officers and should have the following minimum qualification—

(a) a Degree in Pharmaceutical Chemistry or Pharmacy or an Honours or post-graduate Degree in Chemistry;

(b) an intimate knowledge of drug standards; and

(c) adequate practical experience in the manufacture and testing of drugs.

This will ensure a more efficient administration of the Drugs Act, hence statutory provisions should be made in the Drugs Rules.

3.6.1. Administration of the Drugs Act requires specialised knowledge. Training should, therefore, be provided under one of the Foreign Fellowship Schemes. At least two persons should be sent out for such training every year till an adequate number of persons is available.

3.6.2. Some of the States had appointed inspectors, who did not possess the qualifications laid down under the Drugs Rules. Even in the States, where it was better enforced, the number of Drug Inspectors appointed was inadequate. There are no proper testing laboratories to check the quality of products. Invariably, it was entrusted to the Public Health Department laboratories, where the analysts are very often only medical men, with no adequate knowledge and experience in the analysis of drugs. Complaints are frequently being received of varying analytical reports of the same products in the different testing laboratories.

3.7. In order to overcome these defects in the operation of the drug control existing at present, and to bring about a uniformity in the standards of products manufactured, we strongly recommend that the administration of Drug Control should be centralised by bringing control on manufacture, sale, and distribution, which is, at present exercised by the State Drugs Controllers, under the control of the Drugs Controller (India). This will help to bring about a uniform enforcement of the Drugs Act and a better coordination in the administration of the Drugs Act and the Industries (Development & Regulation) Act. The manufacturers, importers, medical men, retail traders and others interested in this industry have also unanimously represented through their respective organisations asking for a centralisation of the entire drug control administration in the country. As "Drugs" is a concurrent subject in the Constitution, we feel, that there will be no difficulty in the Central Government taking over control on manufacture, sale and distribution, which is, at present, exercised by the State Drugs Controllers and bringing it under the control of the Drugs Controller (India).

3.7.1. To enable the Drugs Controller (India) to take over the additional duties indicated in the preceding paragraph and also to further tighten up the existing control over imports, which he is already exercising, we recommend that the set up of the Drugs Control Administration at the Centre should be expanded on the lines given in Appendix No. 11. Once the Drugs Control Administration is centralised, it will require a department of its own in the Health Ministry.

3.8. The control over import of new drugs has been progressively tightened and now there are practically no cases where new drugs are allowed to be imported unless their therapeutic efficacy, pharmacological tests and standards are well established and approved by the Licensing Authority. The other condition is that before permission to import such drugs is given, evidence must be produced by the importer to the effect that such drugs are allowed free sale by the Health Authorities of the country of origin. No trials of new drugs are ordinarily allowed to be carried out in this country, unless the Licensing Authority is satisfied that similar trials have already been carried out in the country of origin. This precludes the possibility of the import of new drugs without clinical trials having been carried out in the country of origin. The standards of new drugs manufactured in this country have to be approved by the Central Government before they are allowed manufacture on a commercial scale.

3.9. To tighten up the control exercised by the Central Government on the entry of sub-standard, misbranded and adulterated drugs, it is necessary to provide adequate testing facilities and appoint additional staff at the ports. We, therefore, recommend the establishment of additional testing laboratories under the Drugs Control Organisation at the ports of entry for primary testing. This will obviate considerably, the delay which at present takes place in getting them tested at the Central Drugs Laboratory. To ensure that the importers have adequate facilities for the storage

of the drugs imported by them, additional staff to inspect their premises and take samples more frequently from their godowns is necessary. In the interest of efficient control on the imports of drugs, it is, therefore, necessary to provide for an adequate number of technical staff at the Centre and ports to help the Drugs Control Officers in their various duties.

4. Facilities for testing drugs

4.1. *Central Government Laboratories.*—The present functions of the two Central Government Laboratories—the Central Drugs Laboratory, Calcutta, and the Central Research Institute, Kasauli have already been discussed. We visited these laboratories and studied their working during our itinerary in these places. The laboratories appear to be sufficiently equipped and adequately staffed for carrying out the duties entrusted to them at present. But with the centralisation of the Drugs Control Administration and improvement in the operation of the Drugs Control throughout the country, we envisage that the work of these laboratories will be greatly increased. Steps will, therefore, have to be taken to supplement the staff and testing facilities as and when the need arises.

4.1.1. During our visits, we noticed that the salaries of the Laboratory Assistants in the Central Drugs Laboratory, Calcutta, who actually carry out the analysis of the products were fixed at a very low scale of pay of Rs. 40—75 and Rs. 60—105. We found that many of them were graduates in science and were well-versed in analytical work. It is very unfair to expect men with such technical training to work on such low scales of pay, which are very nearly the same as paid to uneducated staff and be efficient. In view of the responsible nature of the work, we recommend that these scales should be revised to those paid to Laboratory Assistants in the National Laboratories of the Council of Scientific and Industrial Research, namely:

Graduates—Rs. 100—5—120—8—200—10/2—220.
Intermediates—Rs. 60—4—120—5—150.

Taking into account the importance of the work entrusted to them we also recommend that only graduates in Science should be recruited to these posts as and when vacancies occur.

4.1.2. Another discrepancy that we noticed in the scales of pay of the staff of this Laboratory was that the salaries of the Assistant-Chemists and Assistant Biochemists had been fixed in the scale of Rs. 160—330 while that of Assistant Bacteriologists and Assistant Pharmacologists in the scale of Rs. 160—450. We do not see the need for such a discrimination among the same category of staff, particularly as the same type of statutory work is performed by these people. We recommend that a uniform scale of pay of Rs. 160—450 should be given to all of them and the existing discrimination in their scales which adversely affects their efficiency, should be removed.

4.2. *State Government Laboratories.*—The following table indicates the laboratories and the designation of officers to whom the work of testing drugs has been entrusted by the State Governments:

TABLE No. 31—GOVERNMENT ANALYSTS AND LABORATORIES NOMINATED BY EACH STATE ALONG WITH THE NUMBER OF INSPECTORS APPOINTED BY THEM FOR PURPOSES OF DRUG CONTROL.

Name of the State	Designation of officers appointed as Government Analysts and Names of Laboratories.	No. of Drugs Inspectors.	Remarks
1	2	3	4
PART 'A' STATES :			
Assam. . .	Director, Bihar Drugs Control Laboratory, Bankipur, Patna. Director, Pasteur Institute, Shillong. Director, Haffkine Institute, Bombay. Asstt. Director, Haffkine Institute, Bombay. Associate Pharmacologist, Haffkine Institute, Bombay.	1	While Director of the Pasteur Institute, Shillong has been appointed as Government Analyst in respect of certain items of Schedule C and C(1) products, officers of the Haffkine, Institute, Bombay, have been appointed as Government Analysts in respect of the other Schedule C and C (1) products. For Drugs other than biological and special products. professors of the Chemistry Dept. of the Assam Medical College, Dibrugarh have been appointed as Government Analysts.
Bihar . .	Director, Bihar Drugs Control Laboratory, Patna.	Civil Surgeons of the State are ex-officio Drug Inspectors.	An Officer of Bihar Drugs Control Laboratory has been appointed as Government Analyst in respect of drugs other than those included in Schedule C and C(1). Officers of the Haffkine Institute, Bombay have been appointed as Government Analysts in respect of Schedule C and C(1) drugs as a temporary measure.
Bombay . .	The following officers of the Haffkine Institute, Bombay:— Assistant Director I/C of Pharmacology. Associate Pharmacologist, Department of Pharmacology. Senior Organic Chemist, Department of Pharmacology.	20	

1	2	3	4
PART 'A' STATES—*contd.*			
	Senior Biochemist Department of Pharmacology.		
Madhya Pradesh	Officers of Haffkine Institute, Bombay.	1 All Civil Surgeons and Asstt. Surgeons are ex-officio drug inspectors.	Officers of the Haffkine Institute, Bombay have been appointed as Government Analysts for Schedule C and C (1) drugs.
Madras (including Andhra)	Government Analyst Food and Drugs, King Institute, Guindy, Madras. Asstt. Director and Government Analyst (Drugs special) King Institute, Guindy Madras.	9	
Orissa	Same as under Bombay. ;	1 Civil Surgeons are ex-officio Inspectors.	Officers of the Haffkine Institute, Bombay who have been appointed as Government Analysts for the State of Bombay are also Government Analysts for Orissa in respect of all kinds of Drugs.
Punjab	Provincial Public Analyst and Officer-in-charge, State Drug Laboratory, Kasauli.	2 Asstt. Prof. of Pathology is Special Drugs Inspector (Ex-officio) for Biological products.	Officers of the Drugs Control Laboratory, Ambala Cantt. have been appointed as Government Analysts in respect of drugs other than biological and special products. Officers of the Haffkine Institute, Bombay, have been appointed as Government Analysts for Schedule C and C(1) products.
Uttar Pradesh	Government Analyst U.P. Lucknow University, Lucknow	4	Public Analyst to the Government of U.P. appointed as Government Analyst under the Drugs Act in respect of drugs other than those included in Schedule C and C (1). Officers of the Haffkine Institute, Bombay have been appointed as Government Analysts for U.P. also in respect of Schedule C and C(1) drugs.

1	2	3	4
West Bengal	Government Analyst Provincial Drug Control Laby., School of Tropical Medicine, Calcutta.	6 (and 4 special Hon. Inspectors) ; (All Sub-divisional Health Officers are ex-officio Inspectors).	Director, West Bengal Public Health Laboratory is the Government Analyst for all drugs except Schedul C and C (1) products. No arrangement has yet been made for the testing of Schedule C and C (1) Drugs.
PART 'B' STATES.	No appointment has been made so far.		
PART 'C' STATES			
Ajmer	No appointment has been made so far.		Officers of the Haffkine Institute, Bombay appointed as Government Analysts for all classes of drugs.
Bhopal	Government Analyst State Laboratory, Putlighar, Bhopal.	1	
Bilaspur	Information not available.		
Coorg	Director, King Institute, Guindy, Madras.	1	The Government Analyst (Drugs) and Government Analyst Drugs (Special) of the King Institute, Guindy have been appointed as Government Analyst.
Delhi	Asstt. Director, Haffkine Institute, Bombay.	4	Officers of the Haffkine Institute, Bombay, appointed as Government Analysts for all classes of drugs.
Himachal Pradesh	Director, Central Drugs Laboratory, Calcutta.		Government of U.P. have agreed to the appointment of their Government Analysts as Government Analyst for Himachal Pradesh also in respect of drugs other than biological and special products. The Government of Bombay have been approached for agreeing to the appointment of their Government Analysts as Government Analysts for Himachal Pradesh also in respect of Schedule C and C (1) products.

1	2	3	4
Kutch . .	No appointment has been made so far.		The Chief Commissioner has been advised to take up with the Government of Bombay the question of appointment of officers of the Haffkine Institute, Bombay as Government Analysts for Kutch also.
Manipur . .	No appointment has been made so far.		Government of Assam have been requested to agree to the appointment of their Government Analysts as Government Analysts for Manipur also.
Tripura . .	Information not available.		
Vindhya Pradesh	No appointment has been made so far.	8	Government Analyst is proposed to be appointed after a Notification is issued by the Central Government under rule 1 (3) of the Drugs Rule bringing the provision of the Rules in force in Part C States from a specified date.

4.2.1. It will be seen from the above table that one single laboratory—the Haffkine Institute—undertakes the work of drug analysis for several States, and the Government Analyst for Bombay State, has been appointed Government Analyst not only for Bombay State but for many other States. The names of different States and the class of drugs for which he is appointed as Government Analyst are summarised below:—

Name of State	Class of drugs for which appointed as Government Analyst.
Bombay	(*i*) Biological and special products, *i.e.*, drugs included in Schedule C and C(1) of Drugs Rules 1945.
	(*ii*) Drugs other than mentioned in Schedule C and C (1).
Orissa	Ditto
Delhi & Ajmer States	Ditto
East Punjab	Schedule C and C(1) Drugs only.
Bihar	Ditto
C.P. and Berar (Madhya Pradesh) . .	Ditto
Uttar Pradesh	Ditto
Assam	Ditto

4.2.2. The existing laboratory facilities for testing samples of drugs drawn by Drugs Inspectors are most inadequate in all the State Government Laboratories and result in inordinate delays. It is not uncommon to receive reports of analysis nine months after drawing the samples. To take action after a lapse of such a long period on stocks from which the sample was drawn is thoroughly impracticable. The inadequacy of Government laboratory facilities also restricts the number of samples drawn and analysed. The Chopra Committee had recommended, nearly 25 years ago, the establishment and maintenance of up-to-date laboratories in each of the States. We recommend an immediate implementation of this recommendation. It is also imperative that such laboratories should be well-equipped and adequately staffed to dispose of samples expeditiously. The drug control laboratories should be independent and should not form an appendage to Public Health, Food or Chemical Laboratories. The Heads of the Departments of these Laboratories should be sent for training in the U.K. or the U.S.A., in the latest technique of testing drugs and in this connection, the help of the World Health Organisation (W.H.O.), Technical Co-operation Mission (T.C.M.), and such other bodies should be sought. In examining the question of providing adequate laboratory facilities, advantage should be taken of such institutions as the Indian Institute of Science, Bangalore and the Central Drugs Research Institute, Lucknow. These Institutions have adequate equipment for testing of drugs and it should be possible for them to provide testing facilities to the States concerned.

4.3. *Manufacturers' Laboratories.*—A large number of drug manufacturers have their own testing laboratories. Whilst some of these are well-equipped and adequately staffed, a number of these are far from satisfactory and seem only to serve the purpose of "window-dressing". We have already recommended in the Chapter dealing with Small Scale Private Enterprise, a closer scrutiny of the equipment and testing facilities available, and the qualifications and experience of the staff employed before licensing the firms under the Drugs Act for the various products. We would also recommend that a frequent check of the records and test reports maintained in these laboratories should be made to see that their products are being regularly and properly tested.

4.3.1. Another suggestion to increase laboratory facilities for small scale manufacturers that we have recommended in the same Chapter is that a group of small medium sized manufacturers in various cities or localities should get together and set up joint laboratories on a co-operative basis. We feel that this would be the only way that the small manufacturers will be able to maintain a control on the quality of products made by them.

4.3.2. A number of witnesses have suggested that an organisation such as the Indian Chemical Manufacturers' Association, representing the Pharmaceutical Industry, should set up a control laboratory. One of the most important causes, if not the most important, which has impeded the growth and development of indigenous drug industry, is the lack of confidence among the medical men and also among the public in the products of indigenous manufacture. This Committee has repeatedly been told in most

emphatic terms by medical men, their Associations, Health Institutes, Defence Services and others, that Indian manufacturers have not yet succeeded in creating confidence in their products. Therefore, it is of primary importance that any step which may be taken to bring about this much needed confidence should be given top priority. The Committee recommend that medical profession and pharmaceutical industry should join together in setting up testing laboratories for the purposes of certifying the products made by the Industry, and thus create confidence among the public in the products manufactured. Such a procedure has been adopted in other countries with considerable success and a good example is the Institute of Hygiene, London. This Institute is entirely based on co-operative effort of member firms representing industry on the one hand and professional organisation on the other, and Government do not come into the picture so far as certifying the products is concerned. In this country, two organisations like the Indian Chemical Manufacturers' Association and the Indian Medical Association may well take up this joint effort. If any difficulty as regards finance is encountered, the Government should render assistance by way of grants or subsidies for testing laboratories of the type proposed above. Assistance may also be sought from International Organisations like W.H.O., T.C.M., U.N.I.C.E.F., etc. The Government should recommend such requests for assistance.

4.4. *Public Analytical Laboratories.*—There are at present a small number of Public Analytical Laboratories, approved by Drugs Controllers of different States, where, as provided in the Drugs Act, a large number of drugs are tested on behalf of those manufacturers who have no testing facilities of their own. The following laboratories may be mentioned:—

(1) Italab Ltd.—with branches at Bombay, Calcutta, Madras, Nagpur and Vizagapatam.

(2) Department of Chemical Technology, Bombay.

(3) Therapeutic Research Corporation, Bombay.

(4) Briggs Ltd., Calcutta.

These laboratories serve a very useful function and deserve to be encouraged. The confidence in the results of Public Analytical Laboratories in the country is of primary importance. The Drugs Control Authorities should keep a constant check on their activities and also verify the adequacy of equipment, staff and their technical competency.

4.4.1. When approval is given by the Drugs Controller to a manufacturer to have his products tested at one of the approved laboratories it sometimes happens, that adverse reports are not filed in the records and some machinery is necessary to prevent this practice, which could probably be obviated by insisting that a copy of each of the report may be sent direct to the Drugs Controller.

5. Menace of spurious drugs.

5.1. The problem of spurious drugs has attracted country-wide attention again during the last two years. The menace began during the First World War, when India had to depend for all supplies of drugs on other countries and unscrupulous elements in the drugs trade took advantage of the scarcity of essential drugs like Quinine, and marketed spurious products as genuine ones. This again reached prominence due to scarcity conditions produced during the Second World War. Even after the end of this War, the position has not improved and the spurious drugs trade flourishes to a colossal extent.

5.2. The spurious drug trade thrives due to several causes. First and foremost is the greed for making cheap money, taking advantage of the popularity of a drug by selling clever imitations as genuine products. The second cause is the tendency of the public to buy cheap drugs. The public in this country have yet to learn to buy their supply of drugs from licensed Chemists and Druggists instead of from general provision stores and grocers. A Chemist and Druggist has to keep an establishment in compliance with the various Laws *viz.* The Drugs Act, the Pharmacy Act, etc. He also buys his supplies from the manufacturers directly or from the authorised stockists and distributors. Other shops dealing in drugs buy their drugs usually from the middlemen or commission agents or as they are called 'walking chemists', who have no premises of their own and have no establishment to maintain. These are the persons, who are mainly responsible for the spurious drugs trade, because they sell spurious drugs at a rate, which is much lower than that supplied by genuine manufacturers to the general provision merchants and grocers, which ultimately is purchased by the lay public attracted by the difference in prices. The third cause is the shortage of medicines of established reputation. This shortage of medicines may be real, caused by restrictions in imports, or may be artificial, created by hoarding large stocks of drugs with the expectation that some day prices will rise further and benefit the hoarders. Another important cause is the high retail price of certain drugs such as the anti-biotics, *viz.* Chlortetracyclin, Oxytetracyclin, Aureomycin, Chloramphenicol etc., which are so much in demand due to their life saving property that the average public do not hesitate to buy them when their imitations are offered at lower prices, which spurious drugs manufacturer takes advantage of.

5.3. *Mode of Operations.*—The "modus operandi" in the manufacture of spurious drugs using genuine containers, labels and cartons is as follows: The genuine containers, etc. are collected by "Raddi Wallas' and are supplied in lots to the main shops, 'Jari Purana Wallas' etc. who deal in old bottles. The drug fakers obtain their supply from these dealers at regular intervals. The containers are purchased in a lot and deposited at some place. It is not an offence to have in possession any number of old containers. As soon as an order for spurious drugs is received, the containers are taken to the place, where the filling of the spurious drug is carried out. If a person manufactures these type of spurious drugs, it is neither an offence under the Indian Penal Code nor under the Trade Marks Act or Drugs Act because the drugs fakers never keep with them the dye or the instruments for counterfeiting the labels. His usual defence in a prosecution is that he is not manufacturing any faked drugs but he is having these for his own personal use as empty containers.

5.3.1. Labels of genuine drugs are also printed with the help of printing press owners who act as abettors and print these labels knowing full well that the person who has ordered them is not the genuine representative of the firm. Blocks for printing are destroyed on the spot, as soon as the order is executed. Thousands of labels are printed at one time, so that the question of printing afresh does not arise immediately. Thus, the chief evidence of counterfeiting is lost, although the printing press owner has committed a serious offence. These counterfeited labels are then stored with some relative or friend of the drug fakers, in order that such person might not at all be suspected. Just sufficient number of labels are taken to the place of manufacture, whenever required. If the printing block is not destroyed, it is also deposited in safe custody with some friend or relative. Manufacture of spurious drugs is carried out in unit operations. The raw materials which are used in these drugs (in case of solids it is generally chalk or sodium bicarbonate and in case of liquids, water mixed with some ingredients which smell and look as far as possible like genuine one) are stored at one place, and the place, where actual filling operation is carried out, is different from all the above three places.

5.3.2. These drugs, in turn, are passed on to the public through hawkers and walking chemists, who go from shop to shop and especially to grocers, restaurants, provision merchants and even to some unscrupulous chemists and druggists. These hawkers carry with them some fictitious cash memos and the same is tendered to the buyer. The buyer thinks that he will be protected, if the cash memo is produced. Sometimes, even medical men buy the drugs like Penicillin etc., from these walking chemists, because there is a great difference between the price quoted by them and by other retail dealers. Presumably, these walking chemists sell the goods with the plea that some firm has just gone into liquidation or that there is a general fall in prices. The walking chemists buy the empty vials and bottles and at times collect these from the compounders in hospitals and the same are given back to the manufacturers of faked drugs.

5.3.3. The evil of spurious drugs is in our opinion spreading throughout the country but in a few States due to the active work of the Drugs Control Administration, many cases have been brought to light and, therefore, it appears that it is most prominent in these States. In fact, the spurious drugs fakers have country-wide organisations, but it is most prevalent in Delhi, Calcutta, Bombay, Gwalior, Indore, some parts of Madhya Pradesh, Hyderabad and Saurashtra.

5.4. *Remedies.*—There is no doubt that the existing legislation is inadequate to fight the menace of spurious drugs and this is one of the main reasons, why spurious drugs are marketed on a large scale. The profit earned by the faker is so enormous compared to the punishment imposed, when convicted, that it is always an attractive proposition to manufacture spurious drugs. In a case reported from

Bombay, a person who was prosecuted for manufacturing spurious drugs jumped the bail and during the absconding period, he was again arrested for alleged manufacturing of spurious drugs. It can, therefore, be concluded that drug fakers are not deterred by the existing provisions of the law.

5.4.1. The amendments, that we have suggested to the Drugs Act further ahead in this Chapter will, we believe, set right such short comings in the existing legislation. A stricter and uniform enforcement of the Drugs Act with the suggested amendments will help to eradicate this menace to a large extent.

6. Industries (Development and Regulation) Act, 1951.

6.1. This Act, which came into force in 1951 gives Central Government powers to control Industrial undertakings of all the 42 industries scheduled in the Act, pharmaceutical industry being one of them. All the existing industrial undertakings, which come under this Schedule, are required to get themselves registered under the Act and obtain a licence before producing new articles. New undertakings have to obtain a licence before going into production. The Central Government has powers to investigate into the working of these factories, which come under the Schedule of Industries, revoke registration or licences and assume management or control of undertakings in certain cases. But the control on such factories is restricted to only those that come under the definition of a "factory" as given in the Act. A factory has been defined in the Act as consisting of 50 or more workers working with the aid of power or 100 or more without the aid of power. In the Pharmaceutical Industry out of about 1643 factories, only about 75 factories come under this definition. The value of products made by these 75 units amount to about Rs. 27 crores against a total production valued at about Rs. 35 crores by the entire pharmaceutical industry including Government Factories. Although a greater part of the industry's output emanates from the larger factories, the output of a large number of these small units, which concentrate mainly on one section of the industry *i.e.*, processing pharmaceuticals into dosage form such as ampoules, tablets, capsules, compounded preparations etc. is substantial and cannot be ignored. There is also an economic justification for the existence of smaller factories in the pharmaceutical industry than those envisaged under the definition of a factory in the Act, as certain technical and highly specialised manufacturing processes are best operated in small specialised units.

6.2. As long as the small units conform to certain standards with regard to equipment, location, staff etc., they will be in a position to play an important part in the development of the industry. It is, therefore, necessary to bring such smaller units also under the purview of this Act and facilitate their development. To enable this, we recommend that the definition of a factory in the Industries Act as applied to the pharmaceutical industry should be amended so that given under the Factories Act, 1948 which is as follows:—

"Factory" means any premises including the precincts thereof:

(i) Whereon ten or more workers are working, or were working on any day of the preceding twelve months and in

any part of which a manufacturing process is being carried on with the aid of power, or is ordinarily so carried on, or;

(ii) whereon twenty or more workers are working, or were working on any day of the preceding twelve months, and in any part of which a manufacturing process is being carried on without the aid of power, or is ordinarily so carried on,".

6.3. At present, there is a common set of Rules for all the 42 industries included in the Schedule of the Industries (Development & Regulation) Act. As the problems of the pharmaceutical industry are peculiar in some respects, a separate set of "Rules" for this industry should be prepared by modifying the existing Rules and/or incorporating new clauses wherever necessary, for the additional conditions mentioned in the succeeding paragraphs to be fulfilled.

6.4. *Co-ordination with Drugs Act.*—When a person intends to set up a pharmaceutical factory as defined in paragraph 6.2 above, he will have to apply to the Central Government for a licence under the Industries (Development & Regulation) Act, before setting up the factory or a manufacturing department necessary for the purpose. The Central Government will have to first investigate the advantages that can accrue to the public and the industry by undertaking such production in the quantity proposed, and after satisfying themselves, that it is in the interests of all concerned, give them necessary permission for putting up a factory. After the factory or manufacturing department has been put up, the manufacturer should apply for a licence under the Drugs Act. Permission to operate his factory and market the products should be given only after the Drugs Controller has scrutinised, and satisfied himself that the manufacturer has the minimum requirements of equipment, qualified personnel, premises, sanitary conditions etc. which the Committee have already specified. The licence under the Industries (Development & Regulation) Act should, therefore, be granted subject to the manufacturer obtaining a licence under the Drugs Act. There should be a perfect co-ordination between the licensing under the Drugs Act and the licensing under the Industries Act. Licences will have to be issued under the respective Acts only after consultation between the two concerned Departments of Government.

6.4.1. While on this subject we would like to emphasise that such co-ordination will be greatly facilitated, if the enforcement of the Drugs Act is centralised which we have recommended already. During our visits to the different parts of the country and discussions with the drugs controlling authorities, we have found, that there are serious differences in the interpretation and the methods of administration of the Drugs Act.

6.4.2. In very many States, the Drugs Act is so poorly administered that we found that factories, which had been licensed were located in insanitary places and their premises maintained in no better condition. They also had no proper equipment for manufacture or testing, and neither the manufacturers nor the State were exercising any control on the quality of the products made by them. The products of these factories were a menace not only to the particular

State, in which they were located, but also to the neighbouring States, to whose market they found their way. The people of the neighbouring States were in no way benefitted in spite of the fact that the Act was being administered there in a better manner. When these points were brought to the notice of the State Drugs Controllers, they appeared to be helpless in the matter, either because they were afraid that by closing down such factories, it might lead to unemployment, labour unrest etc., or they had their own misgivings of the powers delegated to them under the Drugs Act to take such steps. It is, therefore, necessary to centralise the administration of the Drugs Act to bring about a uniform implementation of the Drugs Act throughout the country for proper co-ordination with the working of the Industries (Development & Regulation) Act to be possible.

6.5. *New grouping.*—The firms should be licensed to manufacture drugs under the Industries (Development & Regulation) Act according to any of the two groupings given in the classification in Lists A & B of the following table:

TABLE NO. 35

CLASSIFICATION OF PHARMACEUTICAL PRODUCTS

LIST A

1. *Galenicals.*
2. *Anti-Allergic Preparations.*
3. *Anti-biotics.*
4. *Analgesics and anti-pyretics*—e.g. Opium and morphine Preparations, Para-aminophenol derivatives, Pyrazolon derivatives e.g., amidopyrine, Salicylic acid compounds, Cinchona alkaloids and Synthetic anti-malarials.
5. *Anaesthetics.*
6. *Anti-infectious (other than anti-biotics).*
   - *A. Local*—e.g. Anthracene derivatives, phenol, cresol and derivatives, dyes, Furan derivatives, halogen compounds, metal compounds, Sulpha-drugs, etc.
   - *B. Systemic*—e.g., Chaulmoogra derivatives, Cinchona alkaloids and Synthetic antimalarials, Metallic compounds, Hydroxyquinoline derivatives, Anthelmintics, anti-tubercular drugs.
7. *Antispasmodic preparations.*
8. *Astringents.*
9. *Anti-tubercular preparations*—e.g., PAS Salts, Isonicotinic acid hydrazide.
10. *Autonomic Drugs*—e.g., Amphatamine preparations, Ephedrine preparations, adrenaline preparations, Atropine derivatives and analogues.
11. *Cardio-Vascular Agents*—e.g., Digitalis principles and preparations, Strophanthine, Squill preparations, Quinidine.

12. *Diuretics*—e.g., Mercury compounds, Urea and Xanthine derivatives.

13. *Gastro-intestinal Drugs*—e.g., Antacids, Choleretics, Demulcents, Emollients, Laxatives.

14. *Hematics.*—e.g., Anticoagulants such as Dicoumarol, Heparin, Iron and Iron compounds, Brain preparations, Haemostatics such as cyano-cobalamin, Liver preparations, Stomach preparations.

15. *Hormones & Synthetic Substitutes.*—e.g., Adrenals, Ovarian preparations and Estrones, Corpus Luteum hormones, Insulin, Pituitary, Thyroid and parathyroid preparations, Testicular preparations and Androgens.

16. *Agents used in Metabolic Disorders*—e.g., Proteins and Amino-acids, Dextrose, Calcium-salts, Lipotropic agents *e.g.* Choline salts.

17. *Oxytocics*—e.g., Ergot Preparations.

18. *Parenteral solutions.*

19. *Sedatives and Hypnotics*—e.g., Bromides, Chloral derivatives, Hydantoin derivatives, Oxazolidine derivatives, Sulphonals, Barbiturates, Morphine Group, Pethidine.

20. *Vaccines & Sera, Toxins, Antitoxins, Toxoids.*

21. *Vitamins and Vitamin Preparations.*

22. *Unclassified Therapeutic Agents.*

NOTE:—(i) Classification in Group A is of necessity made on very broad lines and indeed it must be so kept so as to give a fair amount of latitude to manufacturers.

(ii) In this classification a certain amount of overlapping is unavoidable due to multiple uses of one and the same drugs.

(iii) Parenteral solutions have been included in Group A and not in Group B because the plant and equipment for manufacture of injectibles is rather costly and most of the manufacturers have great difficulty in utilising their installed capacity economically. It is, therefore, felt that restrictions may be placed on the manufacture of injectibles.

LIST B

(a) *liquid preparations*: (i) local such as Lotions and Liniments, Inhalations, Drops and Sprays; (ii) for internal administration, Elixirs, Mixtures, Solutions and Syrups.

(b) *Granules, Powders, Tablets, Pills, Capsules, Cachets.*

(c) *Lozenges and Pastilles.*

(d) *Bougies, Pessaries, Suppositories.*

(e) (i) *Ointments and Pastes:*

(ii) *Emulsions & Suspensions.*

NOTE:—The main basis of classification in Group B is the plant and equipment required for each group. Thus, more or less same plant and equipment is required to manufacture tablets, pills or granules, or again to manufacture ointments and emulsions or again mixtures, elixirs or syrups.

6.5.1. For example, a factory licensed to make products which come under List [A(2) and List B(b)] should be free to make all products, which come under Anti-Allergic preparations [List A(2)] in the form of tablets, pills, granules, powders, capsules cachets [List B(b)]. It will be only if the firm wants to make any product that does not come under the grouping for which it has been licensed, that it will have to obtain permission of the authority exercising the Industries (Development & Regulation) Act for the new grouping under which this product falls.

6.6. *Development Council for Pharmaceuticals and Drugs.*—To ensure future development of the pharmaceutical industry on the lines of our recommendations, immediate steps should be taken by Government to constitute a Development Council for Pharmaceuticals and Drugs. This Council should be under the Ministry of Commerce and Industry and it should include:—

(1) The Industrial Adviser (Chemicals);

(2) The Drugs Controller (India);

(3) Representatives of the Industry;

(4) Representatives of consumers who in this specific industry are medical men; and

(5) Representatives of the pharmaceutical trade *viz.*, distributors, wholesale and retail pharmacists.

Adequate functions should be assigned to the Council for implementing the recommendations of the Committee. For carrying out these functions, sufficient technical and secretarial assistance should be given.

7. Amendments to the Drugs Act and the Rules thereunder.—

7.1. In addition to centralising the Administration of the Drugs Act, it is necessary to bring about certain changes in the Act and the Rules thereunder for (i) having a more effective control on the quality of pharmaceuticals, and drugs produced and marketed in the country; (ii) bringing about a better co-ordination with the working of the Industries (Development & Regulation) Act, and (iii) eradicating the existing menace of sub-standard and spurious drugs. The Act and the Rules thereunder should, therefore, be amended to provide for the following conditions:—

7.1.1. The term "manufacture" should be defined for the purposes of this Act as under: —

"'Manufacture' in relation to any drug includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution but does not include the compounding or dispensing or the packing of any drug in the ordinary course of retail business."

7.1.2. The term "Drug" should be defined on the lines of the Federal Food Drugs and Cosmetics Act of the U.S.A. This definition is reproduced below:—

> "The term 'drug' means: (i) an article recognised in the Official United States Pharmacopoeia or Official National Formulary or any supplement to any of them; (ii) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (iii) Articles (other than food) intended to affect the structure or any function of the body of man or other animals."

Adoption of such a clause will bring disinfectants, insecticides and contraceptives and the standards for such disinfectants, insecticides and contraceptives, as would be prescribed, under the purview of the Drugs Act.

7.1.3. At present there is provision for the marketing of proprietaries with secret formulae after registration in the Central Drugs Laboratory. This provision should be withdrawn and no patent or proprietary preparations with secret formulae should be allowed to be marketed. Any product to be marketed must have its composition and method of usage published on its label.

7.1.4. Offences under the Drugs Act for trading in spurious and sub-standard drugs should be made cognisable. A deterrent punishment with adequate fine and a compulsory period of rigorous imprisonment should be given.

7.1.5. Giving of adequate publicity of the offender's name and address should be made compulsory.

7.1.6. The trading licence of such an offender should be cancelled and it should be made impossible for him to restart the trade either in his own name or in partnership with others. It is only such deterrent punishment and adequate publicity that will put an end to the trading in spurious and sub-standard drugs, which is so prevalent.

7.1.7. In cases, where a licence has been suspended for the contravention of clauses dealing with trading in spurious and substandard drugs, irrespective of the particular licence to which the offence relates, all other licences should also be suspended for the period and the establishment forced to remain closed.

7.1.8. Suspensions should ordinarily be not given in case of technical offences like non-maintenance of records etc. which should normally be punished by fine unless these offences have been recurring often.

7.1.9. It has to be pointed out that, at present, the possession of spurious drugs is not an offence until the sale of such a drug is effected. Therefore, the possession of spurious drugs should also be made an offence under the Drugs Act.

7.1.10. The possession of any die, plate or other instrument for the purpose of counterfeiting any label or wrapper of a drug, or the possession of a trade mark or proprietary mark for the purpose of falsely denoting that any drug is the manufacture or merchandise of a particular person or firm, should also be made an offence. The punishment should be either imprisonment extending upto a period of three years or a heavy fine or both.

7.1.11. The provision, whereby an Inspector has to take the permission of a District Magistrate or the Chief Presidency Magistrate for search or seizure of adulterated or misbranded drugs should be deleted.

7.1.12. To safeguard the interests of the public against the unsuitable and harmful formulations, sections 12(m) and 33(k) of the Drugs Act should be made applicable to all formulations of drugs and medicines sold in the country.

7.1.13. Minimum requirements of premises, sanitary conditions, equipment and qualified personnel for the manufacture of different products, as indicated by us in Chapter II dealing with Small Scale Private Enterprise, should be specified in the Rules under the Drugs Act.

7.1.14. No license for the manufacture of pharmaceuticals should be given unless the conditions regarding minimum requirements are fulfilled. Licences for the existing factories that do not fulfil these conditions should be revoked.

7.1.15. The Rules under the Drugs Act prescribe the following licence fees for importing, stocking, exhibiting, selling and manufacturing of drugs and medicines:

Form 10.—Licence to import biological and other special products specified in Schedules C and C1 to the Drugs Rules—Rs. 10 for two years.

Form 20.—Licence to sell, stock and exhibit for sale, and distribute drugs other than biological and special products specified in Schedule C—Rs. 5 for two years.

Form 21.—Licence to sell, stock and exhibit for sale and distribute biological and special products specified in Schedule C—Rs. 5 for two years.

Form 25.—Licence to manufacture drugs other than biological and special products in Schedules C and C1—Rs. 20 for two years.

Form 28.—Licence to manufacture biological and other special products specified in Schedules C and C1—Rs. 20 for two years and an inspection fee of Rs. 100 at the time of application for licence.

In order to prevent the unhealthy competition in the profession which has been flooded by unqualified people as a result of charging such low fees, we feel, that the fees for the above licences should be revised and increased as indicated below. While making it clear that the fees should not be viewed as a source of revenue, Drug Control being a social legislation, it is considered that the revenue from an increase in the fees will meet part of the expenditure that has to be incurred for an efficient administration of the Drugs Act as suggested:

Form 10.—The fee for an import licence for the import of any biological or other special products specified in Schedules C and C1 should be Rs. 200 for two years with an endorsement fee of Rs. 100 per endorsement.

A licence fee should be imposed for the import of products not specified in Schedules C and C1 at the rate of Rs. 50 per two years for each manufacturer abroad, a separate licence being given for each manufacturer.

Forms 20 and 21.—Licences for stock and sale of drugs should be in two categories and no trader should be allowed to trade both as a wholesaler and retailer *in the same premises*. Separate licences should be obtained if the same person sets up business both as a wholesaler or a retailer.

In the case of wholesalers, there should be two categories of licences:—

(a) *A distributor for a limited number of manufacturers and importers*:

A fee of Rs. 500 for 2 years should be charged for one or more groups of manufacturers provided he does not represent more than 10 manufacturers. For every additional manufacturer whom he represents, a fee of Rs. 100 for 2 years should be charged.

(b) *A general wholesaler who deals in all types of drugs and medicines from all importers and manufacturers*:

A fee of Rs. 1,000 for 2 years should be charged.

The above scale of fee for distributors should not vary, wherever they are situated, within the territory in which they operate, but for wholesalers who are not situated in big towns like Bombay, Calcutta, Delhi and Madras, the fee should be as follows:—

Cities with a population of	Fee for 2 years.
	Rs.
5,000 and under	5
5,000 to 50,000	20
50,000 to 100,000	50
100,000 to 500,000	100
500,000 and above	200

In cities of Bombay, Calcutta, Delhi and Madras, the fee for a retail licence in Forms 20 and 21 should be Rs. 500 for 2 years for each. For other cities, the same scale of fee mentioned above for wholesalers, should be charged.

Form 25.—A manufacturing licence for drugs other than biological and special products should be Rs. 1,000 for 2 years initially; and for every new product endorsed, it should be increased by Rs. 50 subject to a maximum of Rs. 2,000 for 2 years.

Form 28.—Licence fee for the manufacture of biological and special products should be a minimum of Rs. 2,000 with an endorsement fee of Rs. 50 per item subject to a maximum of Rs. 4,000, for 2 years.

The inspection fee should be Rs. 250 for the first inspection before the grant of a licence and Rs. 150 for every subsequent inspection at the time of renewal.

The inspection of a factory for the manufacture of products specified in Schedule C and C1 of the Drugs Rules should be conducted by a panel of experts at least one of whom shall be a person suitably qualified for such inspection.

The licence issued for manufacture will include the licence for sale by way of wholesale transactions from the factory. If, however, the factory has a separate place where manufactured goods are stocked and sold in the same town, such premises should be licensed as a wholesale distributor. Normally no manufacturer should be allowed to act as a distributor also. Established traders should be encouraged to act as distributors.

7.1.16. Quite a number of pharmaceutical firms do not possess an equipped factory of their own but still market pharmaceutical products by getting their products manufactured in any of the well-equipped and well staffed factories, under the system commonly known as "Loan Licensing". Inasmuch as the country at present possesses more than ample processing capacity this system of loan licensing could be adopted for utilising the surplus capacity. For some time at least this loan licensing system will be necessary. It is recommended that the fee for such loan licences should be Rs. 400 for two years and permission for manufacturing new products should be endorsed on such licence, each endorsement being charged Rs. 20 for two years.

7.1.17. For the proper development of the Pharmaceutical Industry, it is necessary to see that the quality of the crude drugs used as raw material should be ensured. At present, these are handled by people who are not qualified by education or training to do so. In order to improve the quality of the crude drugs available in the market, dealers of such drugs and their premises should be licensed and limited to those who are in a position to guarantee their quality to the manufacturers, and exporters.

7.1.18. It should be made compulsory that every licensed dealer in such drugs should give a warranty about their active constituents.

7.1.19. Manufacturers who obtain their crude drugs requirements directly should license themselves as dealers in crude drugs.

7.1.20. A licence fee of Rs. 100 for 2 years for such registered dealers should be imposed and provision for this made in the Drugs Rules.

7.1.21. Rule 109(1)(a), which reads as follows, is at present applicable to Schedule C drugs. This Rule should be made applicable to all drugs and rigidly enforced. It should apply, in addition to the labels on the containers, to advertisements in Medical Scientific and Trade Journals and the literature distributed by the medical profession and chemists and druggists.

"*Rule* 109(1)(*a*): *Labellings*:—(1) Every phial, ampoule or other container of a substance specified in Schedule C shall bear a label on which is printed or written in indelible ink the following particulars and such further particulars, if any, as are specified in Schedule F:—

(a) The proper name of the substance in letters not less conspicuous than those in which the proprietary name, if any, is printed or written and following immediately after or under such proprietary name."

7.1.22. In the case of combinations, the names of the main ingredients should be displayed in letters of readable size on the labels of the containers and in the advertisements and medical literature.

7.1.23. Sufficient number of well-qualified and properly paid Inspectors should be appointed so that the premises of drug manufacturers, distributors and traders may be more frequently inspected and samples drawn and tested.

7.1.24. The scales of pay of Inspectors should be uniform throughout the country and should start with a minimum of Rs. 275 per mensem. One Inspector should be appointed for not more than 200 selling premises or for not more than 100 manufacturing premises, so that every shop or factory could adequately be inspected.

7.1.25. The Committee has observed that sufficient staff is not provided in many Government Testing Laboratories. They should, therefore, be adequately staffed and the Government Analysts appointed should possess special qualifications in Chemistry in addition to sufficient experience in the modern technique of drug analysis.

7.1.26. The problem of the re-use of old containers has assumed serious proportions. Wide publicity for this is required and the cooperation of the public, the medical profession and chemists and druggists should be sought for the prompt destruction of such containers and thus prevent them from falling into the hands of unsocial elements. Documentary films, cinema slides and posters should be used for giving wide publicity to check this malpractice.

7.1.27. Chemists and Druggists should organise themselves and advertise in the leading professional and Trade journals and newspapers that quality drugs can be had from their Member-Firms who should be made to display, in a prominent place of their shop a badge distributed by the Association. The advertisements should state that the prices of drugs sold by such firms are the fair prices. Such propaganda will not only induce all the chemists to join the Association but also infuse into the minds of the public a sense of confidence in the quality of drugs sold by such dealers.

7.1.28. The use of pilfer-proof closures should be strongly encouraged, and for certain drugs, their use with a seal or stamp should be made obligatory.

CHAPTER VI

RESEARCH WORK

1. Research Work in Europe and America:

1.1. Many fruitful discoveries, in the field of therapeutics, have taken place during the last few years in the continents of Europe and America. Mention may be made of the anti-malarials—(Pamaquinum (B.P.) (Syn. Plasmochin), Mepacrinae Hydrochloridum (B.P.) (Syn. Atebrin), Proguanili Hydrochloridum (B.P.) (Syn. Paludrine); the antibacterials—(Sulphonamide group); remedies for the treatment of shock (Blood Plasma and Sera); specific remedy for the prophylaxis and treatment of Measles (Gammaglobulin), the insecticides (D.D.T. and B.H.C.); and the antibiotics (Penicillin, Streptomycin, Chloramphenicol, Chlortetracyclin, Erythromycin).

1.2. It is interesting to note, that during the War years inspite of the then prevailing unsatisfactory conditions the maximum number of discoveries were made in the realm of drugs. It is significant that, whereas most of the earlier discoveries of this century such as Salvarsan and Bayer 205 came from Germany, considerable contributions have also been made by America, Great Britain and Switzerland to the later ones. The time lag between the laboratory discovery of a drug, its manufacture, and its clinical application has been particularly short. The leadership of Germany in the field of discoveries in synthetic and chemotherapeutic remedies during the early part of this century was due primarily to its having a large dyestuff industry with highly trained chemical staff, and secondly to the collaborative efforts between chemists and medical men. This was in sharp contrast to the individualistic methods of investigation, which were in vogue in the 19th and early 20th centuries in other countries. It was clearly recognised early in Germany and later in England, America and Switzerland, that creative drug research was essentially the collaborative efforts between different groups of scientific workers. There are but few individual workers, who possess all the technical skill and theoretical knowledge required for the development of the whole field of drug and pharmaceutical research.

2. Research work in India:

2.1. *General.*—If India is to solve her difficulties in the field of health and sanitation, it is imperative that drug research should be well organised in a way similar to that in the United Kingdom, America, Germany and Switzerland. Intensive research in Drugs and Pharmaceuticals is an essential part of any health plan for our country. The vastness of the problem can well be judged from the enormous amount of sickness and high death rate that prevails here. Much work on indigenous drugs has been done in India during the