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Training of Expert Staff for the
Quality Control of
Pharmaceutical Preparations

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TABLE OF CONTENTS

	Page
I. DEFINITIONS	1
II. REVIEW OF THE GENERAL SITUATION REGARDING QUALITY CONTROL REGULATIONS	2
III. THE CONTROL FUNCTIONS	3
IV. RESPONSIBILITY OF THE GOVERNMENT	4
1. Administrative and executive branch	5
2. Inspection service	5
3. Laboratory services	6
V. KEY PERSONNEL AND THEIR DUTIES	7
1. The Director	8
2. The Chief Administrative Officer	9
3. The Chief of Laboratories	9
4. The Chief of Inspection Service	10
VI. FORMAL TRAINING	12
VII. TRAINING FACILITIES	19
VIII. TECHNICAL ASSISTANTS	21
IX.. FINAL REMARKS	21
REFERENCES	22

Pharmacy has its primary object the service which it can render to the public in safeguarding the handling, compounding and dispensing of pharmaceutical preparations. It is not a simple matter to accomplish this objective. In retail pharmacy each prescription is dealt with individually by the pharmacist and, therefore, the exercise of the necessary precautions is considered to be relatively easy. Furthermore in extemporaneous prescription work the quantity prepared is usually very small and in countries where the pharmacy laws are adequate and properly enforced the work is all done by the pharmacist himself or under his immediate supervision, and the product is then dispensed to the particular patient for whom the prescription was written. It may be pointed out that the preparation will be consumed by the patient in a relatively short time.

Large scale pharmaceutical production on the other hand presents many problems which are not associated with prescription work, as the manufactured product may receive wide distribution and generally it will not be consumed in a short time. For this reason control methods become mandatory in order to insure the reliability, the safety and integrity of the finished product.

In order to have a perfect quality control for any pharmaceutical preparation three factors are involved: preparation, stabilization, and standardization. The relative importance of each factor depends mostly upon the nature and use of the preparation.

I DEFINITIONS

The study of national regulations pertaining to pharmaceutical preparations in the different countries reveals that a variety of terms are used to designate pharmaceutical preparations and that identical terms may have a different meaning in different countries or under different conditions.

In 1957 the World Health Organization appointed an international group of experts to study the methods used for the examination of pharmaceutical preparations in different countries and to study

principles which could be of help to national health departments and other authorities dealing with this problem. The group noted that the term "drug" and "pharmaceutical preparation" are often used synonymously. They suggested the following definition which is broad enough to include the different types of pharmaceutical preparation and pharmaceutical specialty.

1. A drug (or pharmaceutical preparation) is any substance or mixture of substances manufactured, sold, offered for sale or represented for use in:
 - a. the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof in man or animal;
 - b. restoring, correcting, or modifying organic functions in man or animal.
2. A pharmaceutical specialty is a simple or compound drug ready for use and placed on the market under a special name or in a characteristic form.

II REVIEW OF THE GENERAL SITUATIONS REGARDING QUALITY CONTROL REGULATIONS

It has been estimated that well over one hundred new drugs are placed on the market each year. This large number of new substances presents a certain hazard to public health, especially as a relatively short time may now elapse between the production of a new substance and its use in therapeutics.

The tragedy of thalidomide, the birth of deformed babies to thousands of women who have taken this tranquillizer, has inevitably shaken confidence in present measures to control new pharmaceutical preparations and led to the demand that they be tightened up to prevent anything similar in the future.

The legal provisions in respect to the control of pharmaceutical preparations vary enormously from country to country. Thus the control of pharmaceutical preparations presents a picture of considerable confusion.

This state of affairs will be confirmed by reports presented at this Seminar by the various representatives of the countries of the Eastern Mediterranean Region. It might be mentioned here that the regulations concerned with the control of pharmaceutical preparations in several countries were reviewed in a comparative study of health legislation entitled "Distribution of and Trade in Pharmaceutical Preparations" which was published in the International Digest of Health Legislation (1)

III THE CONTROL FUNCTIONS

The examination of pharmaceutical preparations is a very difficult problem involving precise knowledge of many thousands of compounds. This large number of substances makes it almost impossible for any organization to be familiar with the whole subject.

Imported pharmaceuticals present a particularly difficult problem for government control laboratories because of the lack of knowledge of the manufacturing and analytical control procedures employed by the producers and of the control standards laid down in the country of manufacture. This is complicated further by the great number of pharmaceutical preparations and specialties available on the market. For example, in Lebanon it is estimated that there are about 20,000 products on sale and if only two batches of each product are imported every year it would then be necessary to run 40,000 analytical procedures some of which are fairly complicated if not impossible to perform because of the complex nature of the product.

Therefore, whatever might be done to secure quality control in official laboratories, it is not possible to submit all batches manufactured or imported to such control. Consequently, manufacturers must themselves carry out adequate quality control of all batches for sale to the public and to hospitals, and of all samples delivered to physicians. It is generally agreed that pharmaceutical manufacturers

(1) International Digest of Health Legislation 13, No.3, 1962.

must take the main responsibility for the quality of the preparations they produce since they are in the best position to do so. This subject will be dealt with by Professor Beckett

It is also accepted that laboratory analysis and other forms of control by governments or their recognized agencies are also necessary to reveal any mistakes that might have occurred and as an additional safeguard in preventing unsatisfactory or dangerous products from reaching the consumer. The government control laboratories will be mainly concerned with the control of the finished packaged product which is put into circulation as well as the packaging material.

To sum up it can be said that the most important factors in consistent production of satisfactory preparations are:

a a good system of control by the manufacturer, implying rationally organized and systematic procedures with strict rules in force at all times and b. the employment of adequately trained and experienced quality control supervisors, who are conscientious and alert, as well as thoroughly familiar with manufacturing procedures and aware of the dangers involved in mistakes. No government or external laboratory can exercise such close control over pharmaceutical preparations as the manufacturer.

IV RESPONSIBILITY OF THE GOVERNMENT

The responsibility of the government lies in the establishment of a national Control Authority which will govern the quality control of pharmaceutical preparations. It is suggested that such an agency for quality control could be a part of a ministry or department of health organized as separate division and headed by an officer directly responsible to the minister, or the deputy minister (director general), or chief of the department

The drugs control division should be divided into three branches: Administrative and executive branch; inspection services, and Laboratory services

1. Administrative and executive branch

The functions of this branch has been stated to be as follows. "to draft legislation or regulations, draw up control procedures, keep records of manufacturers and of analysis and inspection work, and issue licences to manufacturers (local and foreign) for the marketing of preparations. It would also be responsible for maintaining statistics on this work, and would provide office management services, keep financial records, and assist in budget work. The administrative branch must be able to obtain legal advice or have people with legal training on the staff".

2. Inspection service

We have mentioned earlier that there are so many pharmaceutical preparations offered for sale in most countries, especially importing countries, that the analytical staff of an official control laboratory cannot examine all of them within any reasonable period of time if at all possible. It is not anticipated that sufficient personnel will ever be available even in the most advanced countries to provide an adequate service for the analysis of every batch of every preparation sold.

Therefore, in addition to the control work done at the laboratory services, it is important to ascertain whether each pharmaceutical manufacturer is able to exercise an adequate control over every batch of all preparations he offers for sale in order that the public and the medical and pharmaceutical professions have adequate protection in respect of the safety and usefulness of the products offered to them.

It is, therefore, one of the most important functions of the authorities dealing with the control of pharmaceutical preparations to arrange for the inspection of pharmaceutical manufacturing plants, with a view of ensuring that they have qualified staff, adequate equipment and proper systems of control over their preparations, beginning with the raw materials, through the production stage and into the final pharmaceutical form. Control of the labelling and the literature accompanying the preparation, which may be considered as important as the analytical control at the laboratory, should be included in the inspection procedure.

If the full possibilities of this branch of the drug control division are employed, much laboratory work will be unnecessary.

Since by the drug plant inspection there is pressure to improve the manufacturing facilities inside the country, it is equally important to apply the inspection procedure to drugs imported to the country. Certain countries have now introduced legislation to make it possible to send inspectors to inspect plants and their quality control. However, the possibility that the exporting country would allow such inspection of its manufacturing plant is an open question.

3. Laboratory services

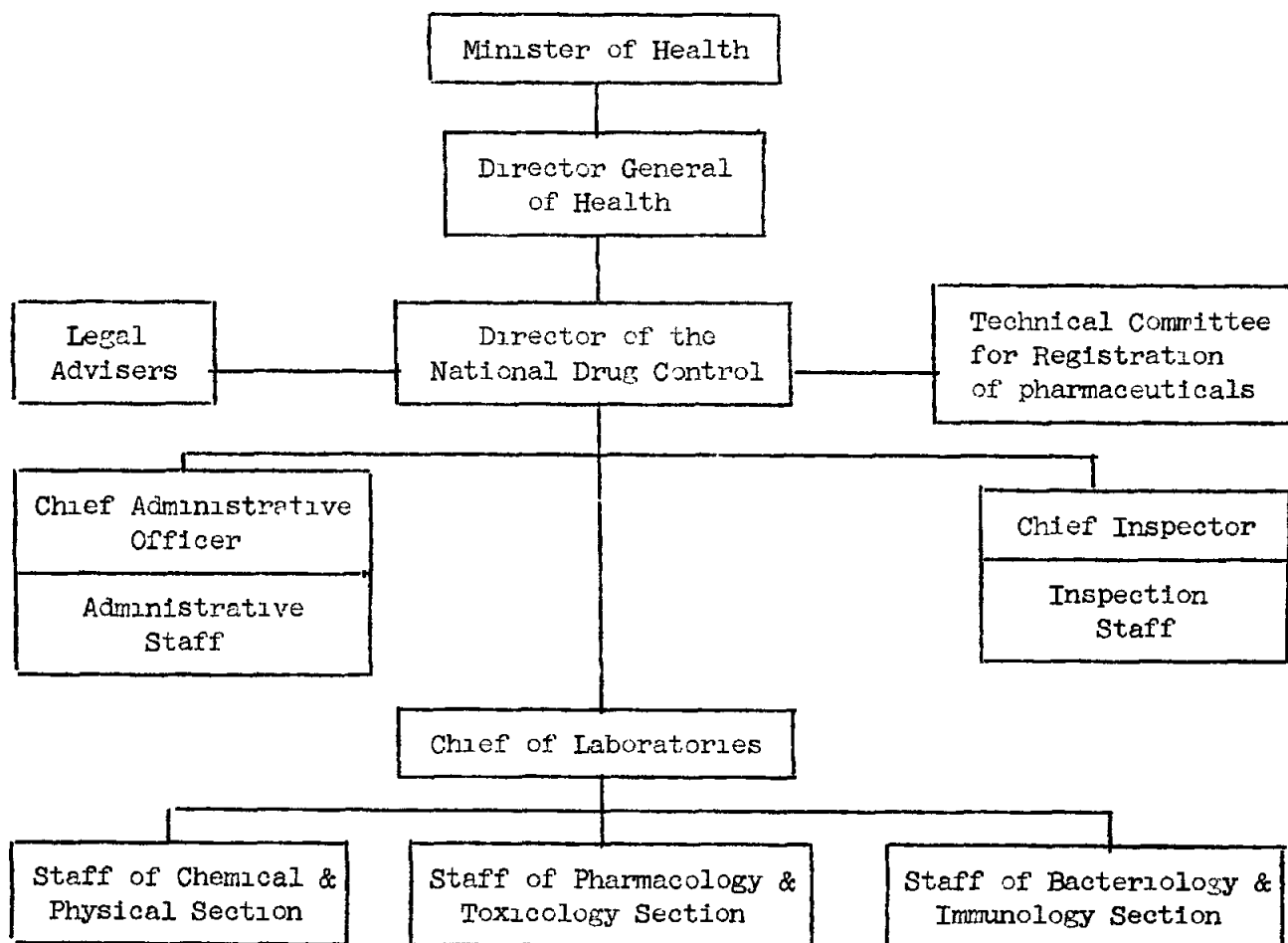
The laboratory services of the drug control laboratory are divided into three sections and the division is based on the kind of work to be done and the educational qualifications of the staff. The sections are described below:

- a. Laboratory for chemical and physical analysis: Chemical and physical analysis of pharmaceutical preparations will be done in this section which should be staffed with specialists in chemical and physical analysis. There should be a head of section who is qualified as a senior analyst by education and experience. Of course this section will be properly equipped with instruments and materials and supplies necessary for all aspects of this work.
- b. Laboratory for pharmacological and toxicological assaying. In this laboratory are performed all tests which require the use of living animals or surviving tissue preparations. The persons employed in this section should have a thorough training in pharmacology and physiology as well as in chemistry.
- c. Laboratory for bacteriological and immunological testing: In this laboratory are performed tests and examinations in which the principles of bacteriology and immunology are employed. Assay of vaccines, toxoids, antisera, etc. will be its work. It will also be responsible for determining the sterility and pyrogenicity of

preparations. Tests of antibiotics based on their effect on bacteria will be done in this section. Experts from this section can also be very useful in advising on matters connected with the sanitary conditions under which drugs and pharmaceuticals are prepared and packaged

V. KEY PERSONNEL AND THEIR DUTIES

The need for expert staff to carry out drug control is very great, particularly in developing countries. In many of these countries usually sufficient means are available to install modern laboratories. It is much more difficult, however, to find trained personnel, without whom the best equipment is worthless. Sufficient staff must be made available for the various sections mentioned earlier, i.e., administration, inspection, and analysis. The arrangement and line of authority for these sections are indicated in the following diagram:



1. The Director of the National Drug Control Authority has the following duties and responsibilities:

- a. The administration and co-ordination of the activities of the three sections of his department.
- b. He makes the final decisions in respect to administrative and enforcement actions.
- c. He determines the administrative policy of his department and gives general direction to his chiefs of divisions.
- d. He keeps contact with the industry on both a technical and management level to encourage mutual co-operation between the government and the industry.
- e. He advises the Minister through the Director General or Deputy Minister in respect to any desirable amendments to the law or regulations.
- f. He fosters useful relationship with foreign or international organizations in the same field of work.

Thus, the qualifications and experience of the Director are a matter of great importance for the success of any national programme for the control of pharmaceutical preparations in the interest of public health. Therefore his training and education should be sufficiently broad to include a good grounding in some of the biological sciences as well as in chemistry, physics and mathematics. A knowledge of physiology, bacteriology and pharmacology is desirable.

In addition to his scientific and technical abilities the Director should have certain basic traits which form the foundation of administrative qualifications. He should have the ability to direct and motivate people. This involves more than merely telling a person what to do. He should be able to inspire his subordinates to produce their highest efficiency. He must have the ability to make unbiased decisions after thorough consultation with members of his staff and his legal and technical advisers. He should have the ability to communicate effectively and be able to "sell" his ideas through verbal and written channels. His directions should be clear and lack ambiguity, at the same time they should be polite and devoid of dogmatism. Above all he should

have a desire for responsibility. Although these are inherent personal qualifications yet they can be acquired either through formal training and education or may be obtained under the direction of a good administrator.

2. The Chief Administrative Officer works in direct contact with the Director on problems related to the following functions:

- a. To draft projected legislation or regulations.
- b. Draw up control procedures.
- c. Keep records of manufacturers (including foreign manufacturers in importing countries).
- d. Keep records of the analytical laboratories and the inspection service.
- e. Issue licences to manufacturers (local and foreign) for the marketing of pharmaceutical preparations.
- f. Maintain statistical records related to control work.
- g. Keep financial records and assist in budget work.
- h. He orders all supplies and equipment approved by the Director.
- i. He keeps record of all expenditures.
- j. He assists in preparing reports.
- k. He files all correspondence and supplies secretarial and clerical service.

The education of the chief administrative officer should be basically in the areas of management and pharmacy administration.

3. The Chief of Laboratories has the following duties and responsibilities:

- a. He assigns work to the various section heads of the laboratory service.
- b. He prepares technical reports to the Director.
- c. He supervises the work of the three sections of the laboratory service. In this respect he must be familiar with the work carried out in the three sections and know in some detail all that is going on in the scientific and technical work performed.
- d. He should maintain a liaison with the chiefs of the control laboratories of the pharmaceutical manufacturers and should be permitted to correspond with them on technical matters.

- e. He is responsible for recommending the purchase of equipment, books, journals and materials and supplies needed by the laboratory services.
- f. He must be familiar with the published scientific work related to drug analysis and with the published recommendation for the use of pharmaceutical preparations
- g. He should develop and improve analytical methods through his readings and by his personal experimentation and research.

In order to perform his duties the Chief of Laboratories will require a good scientific training and considerable laboratory experience. The scientific education and background needed for this key man is similar to that required for the Director.

4. The Chief of Inspection Services is another key man in a drug control administration. His main functions and responsibilities are:

- a. He is responsible for assigning work to his inspectors, for tabulating and co-ordinating their reports, for recommending to the Director any necessary action and for carrying it out.
- b. He should work closely with the Chief of Laboratories and advise the latter in deciding as to what products need to be analysed and what analysis or examinations would be most profitable from an enforcement viewpoint.
- c. He is responsible for the examination of labels and of advertising material if this is controlled by the law. In this work he may need to consult the Chief of Laboratories on technical points.
- d. He should keep record of the number of manufacturers (including foreign manufacturers in importing countries) and their products.
- e. He should keep an adequate file of information about each manufacturer. All violations and the outcome of corrective action should be recorded in these files.
- f. He should have a close liaison with the customs department so that he will obtain information about imports and be able to take prompt action when necessary.

- g. He should be able to train his inspectors to perform their inspection duties properly and effeciently.
- h. The Chief Inspector and his assistants are often referred to as the "eyes and ears" of the administration. The members of this service should be in close contact with the industry and public and it is their duty to observe and report all information relevant to the work of control in addition to their formal reports of inspection.
- i. Since inspectors act as public relation officers as well as intelligence officers of the control organization, they must be able to answer many kinds of questions about specifications, methods of tests and sampling, and good control procedures.

The most suitable education of a chief inspector and his assistant inspectors could be that of a qualified pharmacist with a considerable knowledge of manufacturing procedures, record controls, laboratory examination of raw materials and finished products, plant construction and design, sanitary operations for good manufacturing practice, sanitary control of water and the sewage and rubbish disposal systems, storage practices of raw materials and finished products, suitability of containers. equipment and utensils, and personal hygiene of personnel.

In addition to their technical and professional skills inspectors must possess certain traits and personal qualifications which are so important for the performance of their duties effectively. They must be observant, tactful and discreet and of the highest integrity. They must know very well what their authority is and particularly its limits as well as be familiar with the laws and regulations they are helping to enforce.

In general inspectors must inspire confidence and respect. To gain this confidence and respect inspectors must realize that the object of the enforcement of drug control laws is not only to prosecute manufacturers but to protect public health. Therefore, educational rather than legal action to obtain compliance with the law should be taken whenever this is possible and no immediate danger to the public health is involved. All infractions of the laws and regulations should be brought promptly to the attention of the manufacturer concerned and only those that would have undesirable consequence in terms of public health should be followed by legal sanctions.

VI. FORMAL TRAINING

In my remarks about key personnel and their duties I have mentioned briefly the educational qualifications each should have. It will not be possible to draw in detail an educational programme which they should follow. I could mention, however, that in my opinion these men should have completed a good basic undergraduate programme in pharmacy before they specialize in the respective areas of drug control. Their specialization should culminate with the Ph.D. degree.

It should be mentioned that formal education to these men as well as their subordinates should be supplemented with on-the-job training. Of course continuing education through self experience, reading and studying is of paramount importance for professional growth. The Director and his chiefs of divisions should be encouraged to attend professional and scientific meetings which have a bearing on their work.

Specialized training is closely related to the nature of the various jobs. However, all the professional personnel engaged in drug control should have a general background knowledge of the various activities undertaken by the pharmaceutical industry in the production of pharmaceutical preparation. Furthermore, in addition to having a sound technical background drug control personnel should have the desire and ability to work with others. More specifically, they should possess adequate imagination and initiative to visualize and undertake new approaches to problems, and the perseverance to follow through to completion of each task; good judgement and a willingness to make decisions; the ability to convey ideas clearly and concisely to others; and willingness, when need be, to submerge their personal desires for those of the organization.

1. Specialized training

- a. Administrative personnel Administrative personnel should undergo a thorough training in the areas of economics, accounting, law, and administrative management in addition to their pharmaceutical training. I would not be biased or presumptuous if I say that it is much easier to train a pharmacist in the field of administration than training a person who has studied administration and management

to become a person thoroughly versed with the complexities of the pharmaceutical profession particularly that branch of pharmacy - industrial pharmacy and drug control.

- b. Inspectors: The day to day work of a drug inspector is an exciting drama in which he applies scientific skills and common sense to protection of public health. The inspector's work is seldom routine as he examines, for example, the sanitary conditions in drug establishment, or checks the processing, labelling, and materials used by these firms in the production and distribution of the finished preparations. He reviews analytical work performed by scientists employed by such establishments and, when necessary, makes on-the-spot examination to detect the presence and possible cause of harmful or deceptive adulterations, contaminations or instability of materials used in such products.

The inspector is expected to interview consumers, industry executives, production and research chemists, and others associated with the production, processing, packing, transporting, warehousing and retailing of pharmaceutical preparations. He may also serve as a witness in courts to testify on his findings and observations during a factory or pharmacy inspection or on the results of an investigation with which he was involved. To sum up, the inspector is a busy and dedicated individual who has the personal satisfaction of doing a job recognized by everyone as being important and necessary to the health and welfare of the public.

To become an inspector one must have at least the bachelor's degree in pharmacy from a university of recognized standing. After selection and appointment the new inspector must undergo a period of intensified training off and on-the-job. He gains on-the-job experience by accompanying experienced inspectors on a variety of plant inspections. Off-the-job training often includes attendance and participation in form of training programmes planned of the Chief of Inspection Service.

- c. Laboratory personnel: It is estimated that 80% of pharmaceutical preparations are analysed by physico-chemical methods and the other 20% are examined biologically by the use of pharmacological and microbiological tests. It is therefore evident that the greater number of technical analysts in a drug control laboratory should possess a high degree of specialization in physico-chemical analysis.
1. Physico-chemical analysts: To become a competent physico-chemical analyst, the candidate must have at least a master's degree in pharmacy or physical chemistry, preferably the former from a University of recognized standard. After selection and appointment, the new analyst must undergo a period of intensified training off and on-the-job on the use of the different methods of analysis. On-the-job experience, may be obtained under the supervision of an experienced analyst of the laboratory if such exist. When a national drug control laboratory is not available facilities available in Universities could be used which can be complemented by on-the-job experience in national drug control laboratory of a foreign country. Whenever possible the control laboratories of pharmaceutical firms could be a good source for on-the-job experience.

It must be mentioned at this point that within the area of physico-chemical analysis there is a good deal of specialization. Therefore, the number of analysts to be available must be sufficient to cover the different types of analysis listed below (physico-chemical analysis).

1. Titrimetric Assay Methods
- 1.1 Acidimetric assays
 - 1.2 Alkalimetric assays
 - 1.3 Titrimetric assays Involving Precipitation
 - 1.4 Titrimetric Assays Involving Oxidation and Reduction
 - 1.5 Complexometric titrations
 - 1.6 Titrimetric Assays Utilizing Nonaqueous Solvents.

2. Instrumental Titrations
 - 2.1 Potentiometric titration
 - 2.2 Amperometric titration
 - 2.3 Dead stop end point
 - 2.4 Conductimetric titration
 - 2.5 Coulometric titration
 - 2.6 Spectrophotometric titration
 - 2.7 High frequency titration
3. Gravimetric Assay Methods
4. Instrumental Methods
 - 4.1 Spectrophotometric assays in the ultra-violet
 - 4.2 Spectrophotometric colorimetric assays
 - 4.3 Infrared assays
 - 4.4 Assays involving flame photometry
 - 4.5 Fluorophotometric assay methods
 - 4.6 Polarographic analysis
 - 4.7 Potentiometry
 - 4.8 pH determination
 - 4.9 Nephelometry
5. Gasometric Assay Methods
6. Assays Involving Volumetric Measurement (other than titrimetric and gasometric assays)
7. Assays Depending Upon Measurement of Physical Characteristics
 - 7.1 Assays depending upon measurement of optical rotation (Polarimetry)
 - 7.2 Methods for testing physical constants (e.g., melting points and boiling points, specific gravity and density freezing point, crystallizing point, solidifying point, etc.)
 - 7.3 Refractometry

8. Modern Separation Techniques
 - 8.1 Column chromatography
 - 8.2 Paper chromatography
 - 8.3 Thin-layer chromatography
 - 8.4 Gasé liquid chromatography
 - 8.5 Electrophoresis
 - 8.6 Counter-current extraction
 - 8.7 Molecular sieves.
9. Assays Involving Special Methods
 - 9.1 The assay of enzyme containing substances.
10. Proximate Assays (Alkaloidal Assays)
11. Rheological Measurements
12. Quality Control of Tablets (other than assaying of active constituents)
 - 12.1 Disintegration and dissolution rates
 - 12.2 Size and weight
 - 12.3 Hardness and abrasion resistance
13. Ash Determination of Vegetable Drugs
14. Determination of Moisture Content
 - 14.1 Loss on heating method
 - 14.2 Loss on vacuum drying
 - 14.3 Dean and Stark method
 - 14.4 Karl Fischer method
 - 14.5 Toluene distillation method
 - 14.6 Xylene distillation method
15. Constants of Fats, Fatty Oils, Waxes, Balsams, Resins etc.
 - 15.1 Acid Value
 - 15.2 Saponification value
 - 15.3 Unsaponifiable matter
 - 15.4 Iodine value
 - 15.5 Hydroxyl number of alcohols
 - 15.6 Acetyl value of fatty acids

16. Assay of Volatile Oils (measurement of certain physical characteristics)
 - 16.1 Specific gravity
 - 16.2 Rotatory power
 - 16.3 Refractive index
 - 16.4 Consecaling temperature or point
 - 16.5 Distillation range or limits
 - 16.6 Solubility
 - 16.7 Assay for ester content
 - 16.8 Assay for alcohol content
 - 16.9 Assay for aldehyde content
 - 16.10 Assay for phenol content
 - 16.11 Determination of volatile oil content of crude drugs and oleoresins
17. Assays involving the Use of Immiscible Solvents
18. Radioactivity Measurements
19. Radiotracer Methods
20. Qualitative and Quantitative Evaluation of Crude Drugs
 - 20.1 Macroscopic (whole drug)
 - 20.2 Microscopic (powdered drug)
 - 20.3 Lycopodium count method (quantitative)
21. Limit Tests
 - 21.1 Arsenic limit test
 - 21.2 Lead limit test
 - 21.3 Limit tests for chloride and sulfate
 - 21.4 Limit test for iron
22. Weight Variation
 - 22.1 Weight variation test for hard gelatin capsules
 - 22.2 Weight variation test for sterile solids
 - 22.3 Weight variation test for tablets

23. Containers

- 23.1 Test for limit of alkalimetry of glass
- 23.2 Measurement of light transmission
- 23.3 Chemical resistance of glass containers

24. The Evaluation of Surgical Dressings

- 24.1 Cotton (absorbency test, fiber length)
- 24.2 Sutures (diameter, needle attachment, tensile strength)

11. Pharmacological and Toxicological Analyst

To become a competent pharmacological analyst the candidate must have had a thorough training in the biological sciences and chemical sciences in his undergraduate training and has earned an advanced degree in pharmacology and toxicology. After selection and appointment the new analyst must undergo a period of intensified training off and on-the-job on the use of pharmacological (bioassay procedures) and toxicological methods of analysis. Some of these methods are listed below:

1. Pharmacological Methods

- 1.1 Assay of cardioactive glycosides
- 1.2 Assay of epinephrine (adrenalin)
- 1.3 Assay of insulin
- 1.4 Assay of hormones and hormone products
- 1.5 Assay of curare or curare like substances
- 1.6 Assay of vitamins (A, B, D)
- 1.7 Assay of ergot preparations
- 1.8 Assay of vasopressin injection
- 1.9 Assay of oxytocin injection
- 1.10 Test for histamine like depressor test
- 1.11 Assay of heparin
- 1.12 Test for pyrogens

2. Toxicological Tests

- 2.1 Tests for undue toxicity
- 2.2 Biologic tests to determine the suitability of a plastic for use as containers.

iii. Microbiological Analyst

To become a competent microbiological analyst the candidate must have had a thorough training in the biological and chemical sciences in his undergraduate training and has earned an advanced degree in microbiology. After selection and appointment the new analyst must undergo a period of intensified training off and on-the-job on the use of microbiological testing some of which are listed below:

1. Microbial Assay of Vitamins (niacin, calcium pantothenate, vitamin B₁₂ etc.)
2. Microbial Assay of Antibiotics
 - 2.1 Cylinder-plate method
 - 2.2 Turbidimetric method
 - 2.3 Sensitivity tests of bacteria to antibiotics
3. Sterility Test
4. Antibacterial Tests to determine the antibacterial activities of antiseptics, and germicides.
 - 4.1 Phenol coefficient test
 - 4.2 Other methods
5. Bacteriological Content Test for Gelatin
6. Tests for Stability, Safety, Toxicity, Sterility and Potency of:
 - 6.1 Antitoxins
 - 6.2 Blood products
 - 6.3 Toxins
 - 6.4 Toxoids
 - 6.5 Vaccines
 - 6.6 Tuberculine

VII. TRAINING FACILITIES

We have mentioned earlier that the need for expert staff to carry out drug control is very great, particularly in developing countries. Equally true is the great need for training facilities. We do not know of any country in the world that has a training centre for the whole field of drug

testing particularly in the case of specialized fields. Therefore, we would like to recommend the following plan for training expert personnel in drug control for the countries of Eastern Mediterranean Region.

1. The basic scientific training should be made available at one or more universities of the region.
2. Official control laboratories in the region, if available, should give assistance in the on-the-job training of the personnel who have completed their basic scientific training in a university of recognized standard. If adequate facilities are not available in the official drug control laboratories of the Region, it becomes necessary that new trainees be sent to Europe, the United States of America, or Canada, where such facilities are available.
3. On-the-job or field training could be also accomplished in the laboratories of certain specialized pharmaceutical industrial firms.

In summary it can be said that the training of expert personnel for the quality control of pharmaceutical preparations should be a co-operative effort between the University for basic scientific training, and the official drug control laboratories and the pharmaceutical industry for the field training. In this respect the World Health Organization has an important task to do. In addition to supplying funds for fellowships the World Health Organization should act as an intermediary in connection with these training possibilities. To this end the World Health Organization after consultation with institutions concerned should prepare an approved list of the Universities, official laboratories, and industrial firms in the Region who are willing to train WHO fellows. In preparing this approved list, the World Health Organization should ascertain through visitation by experts that such institutions, particularly the universities who will be primarily responsible for the basic scientific training of WHO fellows, possess adequate facilities for training. The criteria for approving a university should include (a) the number and qualification of the faculty available in the School of Pharmacy and other supporting departments in the university such as chemistry, physics, microbiology, pharmacology etc.;

(b) the apparatus and equipment available in the School of Pharmacy, and other supporting departments in the University; (c) the library facilities available; and (d) the language of instruction. Likewise the criteria for the approval of official and industrial laboratories should include: (a) the number and the competence of the personnel; (b) equipment available; (c) analytical and testing methods used, (d) library facilities, and (e) language.

Whatever training facilities are not available in the region these must be sought in Europe, the United State of America, and Canada.

VIII. TECHNICAL ASSISTANTS

A programme should be established for the training of technical assistants so much needed in laboratories for the quality control of pharmaceutical preparations. This training programme should extend over a period of two years (24 months) beyond the completion of secondary school education.

The programme should be mainly of practical nature and must include courses in chemistry, physics, biology (with emphasis on animal biology), microbiology, pharmacy and pharmacology. Elementary practical courses in instrumental analysis and special laboratory methods should be included. Workshop practice (glass work, metal work, technical drawing, wood work and plastics) is a valuable addition to the programme. A basic programme of this nature will prepare the student to fit into any one of the three areas of the control laboratory.

After selection and appointment the new technician must undergo a period of intensified on-the-job training which prepares him to perform routine analysis or testing in a specific area. It should be emphasized that an assistant technician should work under adequate supervision of the analyst.

IX. FINAL REMARKS

In this presentation I tried to give you the broad outlines involved in the training of expert personnel for the quality control of pharmaceutical preparations. The preliminary remarks about definitions, review of the general situation regarding quality control regulations, and the responsibility of the government are unavoidable introductory material to the subject. I do trust that whatever was mentioned under these sections and the remaining sections of my talk will lead into fruitful discussions of a subject so vital for the production of quality pharmaceutical preparations and pharmaceutical specialties in the countries of the Eastern Mediterranean Region.

In closing I wish to express my personal thanks and appreciation to the World Health Organization for kindly organizing and sponsoring our Seminar. My special thanks and deep gratitude go to Dr. A.H. Taba and his Pharmacy adviser Mr. F.S. Bisharah, who spared no effort for the realization of this Seminar which I earnestly hope will result in specific recommendations and standards for upgrading and safeguarding the developing pharmaceutical industry in the Middle East.

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