



TRAVELLING SEMINAR ON QUALITY CONTROL
OF PHARMACEUTICAL PREPARATIONS

Islamabad/Lahore/Karachi/Teheran/Cairo
9 - 20 March 1970

EM/SEM.QUAL.CTR.PHARM/20a
20 February 1970

ENGLISH ONLY

NATIONAL PHARMACEUTICAL SERVICES
AS APPLIED TO QUALITY CONTROL

by

Fawzie S. Bisharah Ph.C.
WHO Regional Adviser on Pharmacy
and Medical Supplies

PHARMACY

Pharmacy is the health profession which is concerned with the preparation and distribution of medical products.

The Magna Charta of the profession of pharmacy was issued in 1240 when Frederick II, head of the Holy Roman Empire, issued an edict creating pharmacy as an independent branch of public welfare service. Later there were two additional regulations. These three became effective in Latin Europe but not in the Anglo-Saxon world. The regulations separated the practice of pharmacy from that of medicine and acknowledged: "the fact that the practice of pharmacy required special knowledge, skills, initiative and responsibility in order to guarantee adequate care of the medical needs of the people".

With these regulations, pharmacy became a profession and its practice was placed upon a higher ethical plane. The public relations of pharmacy are many and varied in nature, some of them might properly be called professional relations problems, because they involve relationships with other professions such as Medicine.

Dr. Henry Burlage, Dean and Professor of Pharmacy, University of Texas, summarized the history of pharmacy from antiquity to date by the following few lines:

"Pharmacy, with its beginning in the instinctive deference against disease by primitive peoples, developed under several diverse influences. It was part of the work of the priests at first, later it fell among the duties of lay physicians. It found its own form and expression in the culture of Greece and Rome and developed a kind of professionalism in Byzantium, only under the influence of Arabian wisdom and control, did it take firm root in European soil as an institution of public welfare to be respected, regulated and further developed".

The profession of Pharmacy, therefore, grew up in this very Region.

THE PHARMACIST

It is an unfortunate fact of life that sickness or disease does not manifest itself as one single symptom which can be cured with one single drug. As long as there are complicating influences, and there always are, it is not surprising that an attending physician will attempt to prescribe a mixture of two or more products in order to control more effectively the variety of symptoms with which he has to cope.

Such extemporaneous mixtures invariably bring with them certain risks which are minimized when prepared by a professional, the PHARMACIST and for those hospitalized, the hospital Pharmacist.

Shakespeare said: "friendly counsel cuts off many foes". Therefore, the pharmacist makes his contact pleasant, helpful and on mutual happy atmosphere. To make them so, requires understanding of such factors as the needs, conditions, thinking, philosophies and background of those with whom the pharmacist has contact. It requires skill in communication, diplomacy, objectivity in analyzing situations involving conflicts of interest, and willingness to see ourselves through the other person's eyes.

Therefore the Pharmacist as an active member of the health community should enjoy a pleasant and professional personality to fulfil the objectives and prove the very purpose of his existence to the medical and public health departments.

NATIONAL PHARMACEUTICAL SERVICES

What is meant by pharmaceutical services? In some countries pharmaceutical services were limited to inspection of pharmacies and the granting of narcotics' permits. In others it was the establishment of a laboratory for the quality control for pharmaceuticals, poorly equipped and understaffed. Still, in other countries, it was shared with food or sanitary inspectors as a bi-product to control the pharmaceutical manufacturers and so on so forth.

All these functions were carried out under the authority of a Medical Officer of Health. As a matter of fact in some countries, professional pharmacists when carrying inspection of pharmacies, a drug store, a pharmaceutical plant are accompanied by a Medical Officer of Health, a Senior Officer of the Ministry, to give the Pharmacist the necessary executive support, which is vested in the Medical Officer, but not in the pharmacist.

Social progress depends on innovation - the new product, the new method, the new idea - these are the components of the progress of man from the stone age to modern civilization. Perhaps in no area of society is innovation of greater importance than in the health professions, and particularly in the science of pharmacy which has contributed maximally to progress in health care through chemotherapeutic agents.

The practice of Pharmacy, therefore, has changed enormously in recent years. Not so long ago a pharmacist's proficiency could almost be gained by his knowledge of doses and his ability to prepare an emulsion or a pill. To-day, the philosophy of pharmaceutical services has been changed from simple, naive, routine inspection of pharmacies to problematic investigation of minimum levels of stability

quantity and therapeutic efficacy of pharmaceutical forms and pharmaceutical products. To-day's Pharmacist has a big role in the ever changing area of community health, medical care and public health.

Ministries of Health have become fully aware of the importance of having more pharmacists in their employment and particularly specialized pharmacists in the various disciplines of Pharmacy. A new phase where pharmacists are most helpful to the medical profession and useful to the Ministry of Health is in determining the principles, organization and functions of the control of drugs, both in choice and quality, in view of the large consumption of public funds for drugs.

Quality Control of Pharmaceutical preparations is only one important part of pharmaceutical services, however, without a strong administrative machinery behind it does not have the proper support or effectiveness and this is the case in many of our countries.

Later in this paper the administrative machinery will be reverted to, which is the basis of pharmaceutical services. The following paragraphs will demonstrate the principles of quality control.

PRINCIPLES OF QUALITY CONTROL IN INDUSTRY

Large scale pharmaceutical production presents many problems which are not associated with the prescription compounding in a pharmacy, where the quantities of medicaments prepared are usually small and all the work is carried by the Pharmacist himself.

Prescription compounding in a pharmacy requires skill and integrity, but the control involved in these assignments is relatively small. In the manufacture of drugs by an industrial pharmaceutical firm, however, the variety and complexity of operations make it necessary to assign to a separate and independent group of scientists within each company the responsibility for controlling the final product.

Since one of the primary considerations of a responsible drug manufacturer is a deep concern for the reliability and integrity of the finished products distributed to the market under his name, the quality of each batch of each final product is checked for many characteristics by highly

qualified and well trained in administration, with full powers identical to other chiefs of divisions, as shown in Annexes I and II of this paper in the organizational charts.

The development of a quality control laboratory, important as it is, serves an important function and enables the Director of such a division through his Minister to apply the law which is the first step to be introduced for the control in registration, licencing, inspection, import, export and manufacture of pharmaceutical preparations as well as pharmacies, factories and pharmaceutical houses.

In some countries it is feasible to include the "Medical Supply Operation" within this division as suggested in the title above. The procurement, maintenance, storage, control and distribution of all medical and surgical supplies and equipment inclusive of pharmaceuticals, is feasible.

MANAGEMENT OF PHARMACY AND MEDICAL STORES

There has been a long-felt need in this Region and other Regions for the organization of pharmacy and medical supply services to promote high level performance in Governmental and Public Health departments. It is an established fact that the success of any operation depends largely on a genuine and regular line of supply, particularly for medical and public health services most concerned with the promotion of health and control of disease.

The importance of a co-ordinated medical supply service within the Division of Pharmacy and Medical Supplies is progressively being recognized by member Governments in this Region.

Because of the diverse elements of such an administration and unlimited number of special considerations and circumstances involved, it is endeavoured to set forth the basic principles for the economical and efficient handling of Governmental medical supplies and good procurement practices.

National Health Services, in many countries of the World have not yet sensed the importance of pharmaceutical services, nor have they acknowledged

the role that pharmacists can play in public health, in the official control of the practice of pharmacy in general and the control of drugs in particular. National Health Services imply doctors of medicine, medical officers, nurses, public health and sanitary engineers but not pharmacy or pharmacists. In view of the fact that certain countries of this Region were under the British rule, they inherited from the British Administration the half-baked pharmacist, the compounder and the apothecary, the dispenser, the pharmacy attendant or the assistant pharmacist where such pharmaceutical personnel have largely filled the needs of the Ministry of Health which made it difficult for the professional pharmacist to prove his usefulness.

Consequently, pharmacy service does not appear to have earned recognition as a professional department, since in the above-mentioned countries, the pharmacy service is considered a supply function and accordingly in the Central Medical Stores of many countries of this Region, pharmacists are non-existent.

We, in the Eastern Mediterranean Regional Office of the World Health Organization have sensed this problem and encouraged Governments to fuse the medical supply operation, the head of which enjoys better status and more pay than the average pharmacist in civil service, to fuse it within the division of pharmaceutical services and promote it to the status of other medical divisions in the ministry, with a strong director having strong qualities of professional leadership, high integrity and administrative ability, under whose guidance and that of his colleagues, the newly defined philosophy and goals will be attained.

A training programme for career pharmacists in Government service involving management of pharmacy and medical stores is under study by the World Health Organization, to commence in early 1971 in Jordan. In the absence of such a programme, the World Health Organization is doing its best to grant fellowships of various durations, to pharmacists recommended by their Governments to visit other countries in the Region or other Regions which have such integrated services in pharmacy and

qualified scientists, who examine and check the raw materials, and then each batch of the product, during and upon completion of manufacturing operations for identity, purity, uniformity and potency. In addition, after a product has been distributed to the market, responsible manufacturers will perform appropriate tests designed to assure stability and performance.

PRINCIPLES OF QUALITY CONTROL IN THE STATE

Likewise, Governments should apply the same procedures as those of the manufacturers to ascertain the safety of all drugs or pharmaceutical preparations locally manufactured or imported from abroad, including chemicals and raw materials which must have a "standard of quality according to recognized pharmacopoeiae and are to be subjected to testing and assay".

Ministries of Health should evolve a system of certification for pharmaceutical preparations imported or exported, in order to ensure that they had been subjected to the same measures of quality control as applied to drugs and pharmaceutical preparations for consumption in the exporting countries. Good principles of good manufacturing practice and inspection of pharmaceutical manufacturing establishments would facilitate the recognition by importing countries of the validity of inspection carried out in the country of manufacture.

The adherence to such principles for good manufacturing practice and the inspection of pharmaceutical manufacturing plants, is a first and very important step in the quality control of pharmaceutical preparations. A necessary complement is the availability of a strong administrative machinery supported by a laboratory for the quality control of pharmaceutical preparations in order to check the final product and execute the legislation pertaining to it. However, in view of the cost involved and the scarcity of expert workers in this field this is not realizable.

It may be difficult to create laboratories with chemical, pharmacological and microbiological testing facilities which are completely

equipped; in such cases it is advisable to plan a laboratory for analyzing a restricted number of samples of selected pharmaceutical preparations and subsequently expand according to needs.

The principles of quality control in industry stimulated the primary considerations of a responsible drug manufacturer, to a deep concern for the reliability and integrity of the finished products distributed to the market under his name. The quality of each batch is to be checked by highly qualified scientists. In a small branch of Lederle Laboratories in Pearl River, New York, they have twenty-seven Ph.D's, two M.Sc's and one B.Sc. Similarly Governments should at least have a Ph.D. as head of each section and apply equally well the principles of quality control, the organization of which is summarized in three main functions:-

1. To develop a strong administrative machinery (A Division of Pharmacy and Medical Supplies).
2. To employ nationals highly qualified in pharmaceutical sciences and arrange for their specialization either through bilateral assistance or Government funds.
3. Establish within the Division of Pharmacy and Medical Supplies a fully equipped and well staffed Laboratory for the quality control of pharmaceutical preparations.

Experience revealed that in countries of this region the difficulty in the organization of an effective control seems to be lack of proper administration rather than qualified personnel. There are 19 schools of Pharmacy in this region graduating approximately 300/400 men and women every year, who would need specialization in the various fields of pharmaceutical administration and quality control of pharmaceuticals. They would need training in pharmacy affairs, inspection and control of pharmacies, drug stores, pharmaceutical factories, importers and distributors. In pharmaceutical chemistry as analysts, pharmacology and microbiology. This paper touches on the organization of a "Division of Pharmacy and Medical Supplies" within the framework of the Ministry of Health, to be headed by a Division Chief of a senior status, highly

medical stores, to get experience which will help them in the performance of their duty when they return home. Others have been granted academic fellowships of two years post-graduate work in pharmacy for quality control of pharmaceutical preparations of hospital pharmacy administration.

The importance of a co-ordinated pharmacy and medical supply services is progressively being recognized in this Region, few of our Member Governments have requested assistance in this respect from the World Health Organization. Jordan and Libya have integrated the medical supply operation within the pharmaceutical services under one division in the Ministry of Health headed by a pharmacist who enjoys a senior status similar to other Directors in authority and in compensation. Other countries are working up towards realizing it.

In large countries like Iran, Pakistan and the United Arab Republic this is not feasible, however, each service is independent from the other, well established and headed by senior officers. It is interesting to note that in the Sudan and the United Arab Republic the chief of the medical supply operation and medical stores is a medical officer and enjoys the position of an under-secretary of health, directly responsible to the minister. In Pakistan there are three medical stores in Karachi, Lahore and Dacca altogether there are six medical officers assigned to these stores. This is definitely a waste of medical manpower which is very badly needed in such developing countries, in medical care and public health.

DIVISION OF PHARMACY AND MEDICAL SUPPLIES

To be headed by a director, director-general or an under-secretary as the case may be in each individual country, (A PHARMACIST), with the necessary assistants, secretarial and administrative staff, this division is to be sub-divided into pharmacy affairs section and medical stores.

I Pharmacy Affairs Section

To be headed by a Chief Pharmacist with assistant, secretarial and administrative staff as may be found necessary and is to be sub-divided as follows:

1. Department of registration and licencing

To register all pharmaceutical institutions, pharmaceutical preparations, locally manufactured or imported from abroad, all pharmacists and pharmacies and workers in this field.

2. Department of inspection and control

To be headed by a chief inspector (a pharmacist) and an adequate number of other inspectors, all pharmacists, trained for the purpose, to carry out a countrywide inspection of pharmacies, drug stores, manufacturing plants, whether in the private or the public sectors. To check Government property, verify inventories of all hospitals, health centres and health establishments of all kinds.

3. Department of production of pharmaceuticals, import and export of drugs

Manufacture of pharmaceuticals as well as import/export of drugs, raw materials, dangerous drugs and narcotics. To promote good manufacturing practice in the production, to formulate generally acceptable requirements in the production and to enforce the ethical and scientific criteria for pharmaceutical **advertising**.

4. Department of hospital pharmacy

To supervise and implement hospital pharmacy administration, drug information center, central sterile supply service in the hospital, central supply of hospital equipment, furniture, etc. and the publication and periodical revision of hospital formulary system as well as production of parenteral solutions.

5. Laboratory for the quality control of pharmaceutical preparations

To be headed by an academically qualified analyst for the testing of all pharmaceuticals, locally manufactured, exported or imported from abroad. The laboratory should carry on physico-chemical analysis, microbiology and pharmacology as well as a research unit.

II The Medical Stores

To be headed by a pharmacist, supervisor, storekeeper, director, superintendent, call him what you please, these titles are common in the various countries of the Middle East. The head of the medical stores is to be assisted by pharmacists and others as required by the following sections:

1. The medical section of the stores

Houses drugs, galenicals, pharmaceutical preparations, dressings, sera and vaccines, disinfectants and insecticides, etc.

2. The surgical section of the stores

Houses surgical instruments and equipment, surgical and medical sundries, rubber goods, dental equipment and appliances, X-ray equipment and dark room accessories, etc.

3. The laboratory section of the stores

Houses laboratory furniture, equipment, sundries, glassware, reagents, chemicals and blood bank equipment and accessories.

4. The equipment section of the stores

Houses furniture, bedding, linen and clothing, stainless steel-ware, enamelware, kitchen utensils and equipment, crockery, cutlery, cleaning materials, stationery and printed matter.

Workshops - for repair and maintenance of medical equipment:

- a. Electrical workshop
- b. Mechanical workshop
- c. Carpentry
- d. Tailoring
- e. Mechanical transport and spare parts.

THE ABOVE BASIC SECTIONS OF THE MEDICAL STORES MAY BE
AMALGAMATED, SUBDIVIDED FURTHER, SUBJECT TO THE SMOOTH WORKING CONDITIONS

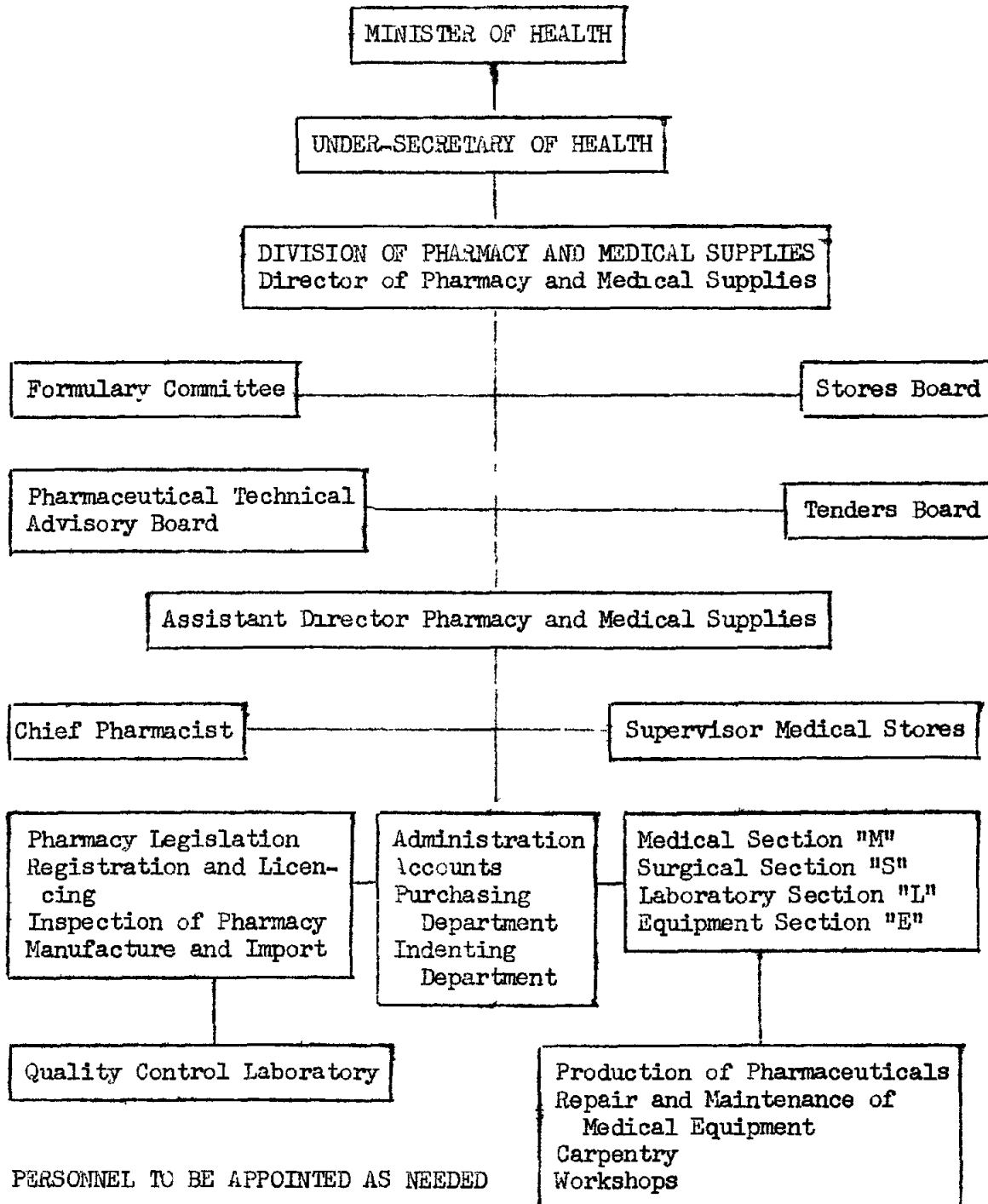
These are but guiding lines towards the establishment of pharmaceutical services which would develop the pharmacy division to its highest, give authority and executive powers to its personnel, promote them to high grades and place all other services in the ministry under their goodwill and cooperation.

Many a pharmacist declines, out of professional pride, to take over such odd jobs in the Medical Stores, such as surgical equipment, instruments, repairs, furniture, etc. The answer to this has been known all over this Region - "It is easier to train a pharmacist in administration, rather than teach a lay administrator, Pharmacy".

Incidentally, Jordan and Saudi Arabia have recently built up such a department and constructed medical stores for the purpose. Cyprus is on its way in the construction of Central Medical Stores; Libya, however, is planning for the construction of a compound to house the division of pharmacy and medical supplies as detailed before, for which the Ministry has allocated two million pounds Libyan.

See Annexes I and II - Organizational Charts for the development of Pharmacy and Medical Supply Division and Laboratory for the Quality Control of Pharmaceutical Preparations, respectively.

ORGANIZATION PATTERN OF THE PROPOSED DIVISION
OF PHARMACY AND MEDICAL SUPPLIES



PLAN ORGANIZATION FOR THE CONTROL OF PHARMACEUTICAL PREPARATIONS