WORLD HEALTH ORGANIZATION
REGIONAL OFFICE
FOR THE EASTERN MEDITERRANEAN

ORGANISATION MONDIALE DE LA SANTE
BUREAU REGIONAL
POUR LA MEDITERRANEE ORIENTALE

TRAVELLING SEMINAR ON QUALITY CONTROL
OF PHARMACEUTICAL PREPARATIONS
Islamabad/Lahore/Karachi/Teheran/Cairo
9 - 20 March 1970

EM/SEM.QUAL.CTR.PHARM/16
5 February 1970
ENGLISH ONLY

PHARMACEUTICAL QUALITY CONTROL LABORATORIES AS A SEMI-INDEPENDENT UNIT OF THE PUBLIC HEALTH LABORATORY SERVICES

by

Dr. H.R. Husseini
WHO Regional Adviser on
Health Laboratory Services

INTRODUCTION

The argument to evolve pharmaceutical quality control laboratories as a semi-independent unit in the Public Health Laboratory services rests on many factors, the most important of which revolves around socio-economic, administrative and technical status. These factors should be given thorough consideration before developing drug control as a completely independent and autonomous unit.

The need for pharmaceutical quality control is now increasingly felt. Many countries in the Region produce their medicine and all of them import drugs from outside. Therefore all measures designed to ensure the uniform output of batches of drugs that conform to established specifications of identity, strength, purity, etc., should be strictly applied.

In developing countries, the planning for the establishment of these activities should be fully studied, and a suitable plan should be adopted. Many developing countries are now in the process of organizing or re-organizing their Public Health Laboratory Services. This is an

opportune time to consider the feasibility of establishing in them units for drug control at the central and peripheral levels.

Assessing the conditions in developing countries the following important facts emerge:

1. The great majority of developing countries are still in the communicable diseases era. The major causes of morbidity and mortality continue to be bacterial, parasitological, viral and rickettsial infections. Other chronic non-microbial diseases are present, but they are still minor when compared with the microbial infections.

The most important medicines to be utilized are the antibiotics. Accordingly testing for antibiotics should be provided in detail and this is mostly dependent on chemical and biological tests.

2. The socio-economic development in these countries dictates restrictions on expanding these services that are bound to duplicate other existing services in personnel, equipment and supplies as well as accommodation and administration. It is important to judge the suitability of a programme having in mind the means and resources available. In general the establishment of a completely separate drug control laboratory is costly. However if integrated as a semi-independent service unit in the public health laboratories, it can be converted, so that productive forces could be released, leading to long-term benefits, if directed to socially useful ends. Therefore it is important that the maximization of welfare and the complementarity of services should play a great role in determining the establishment of such a service.

3. The lack of adequate expert personnel does not permit expanded activities and may allow only the performance of limited but essential procedures that could involve other staff members of the laboratory. The experts responsible for supervising the control of drugs should possess the qualifications of scientific education and the practical experience required. Their education should include the study of an

appropriate combination of chemistry, biochemistry, microbiology, pharmaceutical sciences, technology and toxicology, physiology and histology and other related sciences. They should also have ample experience in the control of drugs. These experts should have no interest outside their work, so that they are not prevented or restricted from devoting the necessary time to their assignment responsibilities, and so that no conflict of financial interests is entailed.

Moreover an adequate number of technically trained personnel should be available to perform the control operations, in accordance with established procedures and specifications.

Although qualified personnel is rare, many of them are already members of the public health laboratories staff and could thus be utilized in drug control.

THE ADMINISTRATIVE FACTORS

Forming a new unit entails many administrative factors:

1. Legislation: A special legislation should be promulgated, giving rules and regulations for the new department, its capacities and its limitations.

2. Accommodation: Premises with new equipment and supplies as well as auxiliary personnel will be required, demanding additional expenses. These premises need also common services which are usually to be adequately found in the public health laboratory, e.g. electricity, gas, furniture, etc.

3. A host of various supplies and equipment which are necessary in the laboratory.

4. New personnel with suitable extra qualifications is required. Many other problems will arise as to the status of personnel and their relationships with other similar workers.

5. Many facilities available will be duplicated e.g. washing rooms, maintenance facilites and library.

It is clear that these problems will minimally arise if this set-up was considered as a semi-independent unit of the public health laboratories.

THE TECHNICAL FACTORS

Many technical factors will also arise as a consequence of having a completely separate unit.

1. Duplication of equipment and supplies.

These laboratories will definitely need photometres, electrophoresis, thin layer chromatography, chemicals and other equipment, which are already available at the Central Public Health Laboratories and could easily be utilized by the new unit, if accommodated in the Central Public Health Laboratories.

2. Training of personnel.

The training of laboratory personnel has many things in common and yields itself to sharing the available facilities and to co-operation between the scientific staff. Hence the choice for training should be based on:

(a) Availability of instructors to ensure the quality of training
(b) Availability of the necessary equipment and supplies
(c) Availability of adequate working space in a health environment
(d) Accessibility of the place for trainees and instructors
(e) Availability of reference books, library facilities and training aids.

These are the material needs for teaching, but there are also the moral needs, namely the co-operation of the teaching staff and the trainees.

The training programme will be cheaper to finance if several categories of trainees participate in common classes for parts of their curriculum and whenever the expenses of equipment and supplies are rather high.

This training should be done in the Institute which will make it less expensive, and in developing countries the public health laboratories enjoy having the physical and moral needs for training and present suitable conditions for it.

This training includes, microbiology, serology, biochemistry, histopathology, toxicology, etc. which could be easily undertaken by the public health laboratory staff.

Another type of training is by apprenticeship, which can also easily be done at the laboratory. Moreover facilities will be available for in-service training.

THE PUBLIC HEALTH ASPECTS OF DRUG CONTROL

Drugs play an important role in public health; their availability, their standard and quality being of the utmost importance for the control of endemic and epidemic diseases. The drugs of deficient quality will allow the continuation of cases, which could act as foci for the dessemination of disease and the exaggeration of the outbreaks. These drugs should be put under surveillance like micro-organisms. The changing patterns of disease, the ecology of bacteriological agents, as well as their susceptibility to antibiotics and drugs, play an important role in the extent of an infection spread. Public health laboratories are entrusted with epidemiological surveillance activities, which give the information previously mentioned on micro-organisms. These activities demand a close relationship between pharmaceutical quality control laboratories and the public health laboratory. This end can best be achieved if both are in close contact administratively, technically and organizationally.

Provincial laboratories can also assist in checking the quality of drugs by running preliminary tests on them, e.g. physical appearance, etc., and could be an integral part of the drug control machinery, by becoming aids in collecting and referring samples to the Pharmaceutical Control Laboratories.

CONCLUSION

The establishment of a Pharmaceutical Quality Control Laboratory as a semi-independent unit in the public health laboratory satisfies the maximization of welfare and complementarity of services, more than their development as completely separate administrative and technical units.