WORLD HEALTH ORGANIZATION
REGIONAL OFFICE
FOR THE EASTERN MEDITERRANEAN

ORGANISATION MONDIALE DE LA SANTE
BUREAU REGIONAL
POUR LA MEDITERRANEE ORIENTALE

SPECIAL GROUP MEETING
ON PHARMACY EDUCATION

Beirut, 19-24 October 1970

EM/GR.MTG.PHARM.EDUC/5
23 September 1970

ENGLISH ONLY

THE ROLE OF THE PHARMACIST IN THE QUALITY CONTROL OF PHARMACEUTICAL PREPARATIONS AT BASIC DEGREE LEVEL

by

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INTRODUCTION

Few academic professions have curricula more overcrowded with disciplines that compete for the student's time than the pharmacist's. This is clearly demonstrated in the in-depth study Professor Haddad has presented in his Survey Report of Schools of Pharmacy in the Eastern Mediterranean Region[1]. One has to be discriminating indeed when deciding how to balance a (usually four-year) curriculum with respect to lectures and laboratory and practical training to prepare the students for the various tasks they will have to undertake in their future activities.

In most countries of the world the curricula for the study of pharmacy are at present under discussion and being revised to meet new demands, which of course vary depending on, among other factors, socio-economic conditions and the traditional tasks of pharmacists in the respective countries.

The multi-disciplinary character of pharmaceutical education forms a necessary background for the important role of the pharmacist in the field of quality control of drugs.

PRINCIPLES OF QUALITY CONTROL

Being an abstract concept, quality control cannot easily be defined. It certainly is no longer sufficient to state that a product shall comply with

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[1] EM/PHARM/39

established specifications. The present complex situation with a wide variety in the structure of drug manufacturing made it desirable to formulate general principles on which quality control should be based.

Such principles were formulated by the twenty-second Expert Committee on Specifications for Pharmaceutical Preparations[1].

Generally speaking, the conception of quality refers to the suitability of a product in relation to its intended use. The quality of drugs available in commerce (once the efficacy and safety have been established) is judged by identification, and tests measuring strength, purity and other relevant characteristics - that is, conformity to established specifications.

Quality control is practised to achieve sustained and uniform manufacture of products of desired quality levels. The essential factors in this respect are:

(a) Product quality specifications, and

(b) production control.

Product quality specifications are necessary to determine the suitability of starting materials for use in manufacture, and to determine the quality of end products. Such specifications are usually found in official compendia such as pharmacopoeiae, codices and formularies.

The second, equally important, aspect of quality control of drugs in their dosage forms is production control.

There are three main aspects of production control: firstly, the suitability of manufacturing premises and equipment and the availability of competent staff; secondly, process control to ascertain that the established

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[1] Wld Hlth Org. techn. Report Series, 1969, No. 418, Annex 1

production procedure is followed and that no mix-ups and contamination occur; and, thirdly, final control of the end products to ensure that they comply with the established specifications.

WHO PROGRAMME ON QUALITY CONTROL OF DRUGS

The following is an attempt to summarize the WHO activities in the field of pharmaceutical quality control.

Specifications

The first edition of the International Pharmacopoeia was published in three volumes: 1951, 1955 and 1959. A second edition[1] was published in 1967 containing 555 monographs and 69 appendices.

Modern analytical methods used in pharmaceutical quality control are described in the appendices to the second edition of the International Pharmacopoeia; for example, infra-red spectrophotometry, polarography, chromatography (column, paper and thin-layer), radioactivity, non-aqueous titration, and determination of melting-range and melting-point and identification of substances by the Kofler method.

Although some of the methods such as polarography have not been applied to the requirements of any particular monograph, it was thought that the International Pharmacopoeia should be representative of the best current practice in drug quality control and that they were a desirable addition.

Specifications for Reagents

During the work on the first edition of the International Pharmacopoeia it was felt that more detailed specifications for reagents used in conjunction with the assays and tests included therein should be drawn up.

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[1] World Health Organization (1967) Specifications for the quality control of pharmaceutical preparations - second edition of the International Pharmacopoeia, Geneva

A working group was organized and the work on specifications for reagents, based on existing specifications and on collaborative work of experts, was later co-ordinated with the preparation of the second edition of the International Pharmacopoeia.

The "Specifications for Reagents mentioned in the International Pharmacopoeia" were published in English (1963) and in French (1966).

Chemical Reference Substances

Spectrophotometric assays and identification tests, as well as paper and thin-layer chromatographic purity tests, applied in the International Pharmacopoeia, require the use of chemical reference substances. WHO provides a number of International Chemical Reference Substances which are established upon the advice of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. The characteristics of the substances selected are determined by the WHO Centre for Chemical Reference Substances in Solna, Sweden, in collaboration with specialists designated by WHO.

At present, about 40 substances are available from the Centre, mainly steroids, cardiac glucosides, semi-synthetic penicillins and a few other substances.

There is little doubt that reference substances will be increasingly used in the quality control of drugs in the future, and the Centre invites the close collaboration of all national authorities concerned with the establishment of chemical reference substances. By these means, it is hoped to achieve uniformity and, as far as possible, actual identity in the reference substances that are established.

Further Work on Speficications

The Expert Committee on Specifications for Pharmaceutical Preparations recommended at its twenty-third meeting in Geneva, 25-29 November 1969[1], a number of additions and amendments to the second edition of the International Pharmacopoeia.

The additions include monographs for anti-tuberculosis drugs widely used in WHO/UNICEF-assisted projects, monographs for radioactive pharmaceuticals and a general description of newer methods used for the quality control of drugs. It is expected that they will be published next year as a supplement to the second edition of the International Pharmacopoeia.

The twenty-third Expert Committee on Specifications for Pharmaceutical Preparations also recommended that the International Pharmacopoeia be revised as soon as possible and recommended the addition of more than one hundred monographs. It is expected that a large number of chemical reference substances will be needed in connexion with these.

Production Control

The Twentieth World Health Assembly (1967), in a resolution, requested the Director-General inter alia "to formulate as soon as possible principles for quality control procedures such as should be incorporated in good drug manufacturing practices".

In August 1967 a group of specialists met at WHO Headquarters in Geneva to assist in the preparation of requirements for good practices in the manufacture and quality control of drugs. The draft text was sent to all Members States of WHO for comments and it was also discussed at a meeting of the

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[1] WHO/PHARM/70.456

Executive Board and the World Health Assembly in 1968. All comments received were considered by a WHO Expert Committee which met in Geneva in October 1968, and a revised text was prepared.

In its resolution WHA22.50 the World Health Assembly recommended that Member States adopt and apply these requirements.[1]

Inspection of drug manufacturing establishments by the national control authority is being introduced in an increasing number of countries and these requirements constitute a guide and framework which should be adapted to meet the actual needs by those responsible for carrying out manufacturing procedures. Inspection to such agreed requirements is a concept that is becoming widely accepted and implies that the responsibility for the quality control in manufacture is shared between the manufacturers and the national control authorities.

International Nonproprietary Names

In order to avoid the confusion which arises when different nonproprietary names are used for the same substance, WHO has operated since 1952 a programme for the establishment of international nonproprietary names.

International nonproprietary names can be requested by national authorities, manufacturers and other interested persons and the proposed international non-proprietary names are selected in accordance with the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances and the General Principles for Guidance in Devising International Nonproprietary Names for Pharmaceutical Substances adopted by the World Health Assembly.

The names are first published in lists of proposed international non-proprietary names in the WHO Chronicle. Objections to proposed international

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[1] Wld Hlth Org., Off. Rec. No. 176, Annex 12

nonproprietary names can be lodged within four months of their publication in the WHO Chronicle. In the absence of objections, the names are republished as recommended international nonproprietary names.

Up to the present, over 2 600 names have been published in 24 lists of proposed international nonproprietary names, about eighty-five per cent, of these names being recommended names. Since 1968 lists have been published twice yearly and include graphic formulae.

International nonproprietary names are used in the titles of monographs and in the text of the International Pharmacopoeia and in many national pharmacopoeiae. They are also widely used throughout the world for regulatory, labelling, scientific and other purposes.

CONCLUSION

The above brief review is given with the intention of demonstrating the importance WHO attaches to the quality control of drugs. This is further emphasized by the fact that several regions of the Organization have arranged seminars and training courses on this subject during the last few years.

In almost all countries there is at present a shortage of qualified experts in this field. Post-graduate education is, of course, indispensable for people in responsible positions in government service, whether engaged in national control laboratories, inspection of pharmaceutical factories or pharmacies, or in administrative positions where decisions have to be taken based on scientific reports. Inspectors may have specialized in pharmaceutical technology but will, for example, also be expected to judge the adequacy of control facilities and procedures.

Deeper knowledge is also required by pharmacists engaged in quality control in industry and hospital pharmacies.

The dispensing pharmacist is responsible for the proper handling and storage of drugs from the time they are received from the manufacturers until they reach the patient. It is extremely important that he is aware of the adverse factors that can influence the potency and strength of the drug during this period. This problem is accentuated in countries with a hot climate.

It is therefore indispensable that in the curricula for undergraduate training sufficient time is devoted to the basic and applied sciences such as organic, inorganic and analytical chemistry, physics and mathematics, pharmaceutical microbiology, etc. Laboratory courses in analytical chemistry should familiarize the students with classical analytical methods and also the most commonly used physico-chemical methods. With regard to more sophisticated methods, such as gas-liquid chromatography and infra-red spectroscopy, attempts should at least be made to arrange practical demonstrations.

The objectives of undergraduate training in pharmaceutical quality control should be two-fold: to create a sound understanding of modern concepts in pharmaceutical quality control and to form a solid background for post-graduate specialization.