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 - 21 March 1970

EM/SEM.QUAL.CTR.PHARM/22
30 March 1970

ENGLISH ONLY

SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS AGREED BY THE TRAVELLING SEMINAR ON QUALITY CONTROL OF PHARMACEUTICAL PREPARATIONS

The Seminar agreed that a number of problems needed further investigation in the different countries of the Region at national level, or during the course of future WHO activities, and passed the following Recommendations:

I

effective quality control of imported or locally manufactured drugs and medicines should be started or developed in every country of the Region with the support of the Government and/or of other sources, preferably through the formation of an independent unit or, if not possible, then as a semi-autonomous unit for this purpose within the national health laboratory;

II

a) a pharmaceutical reference laboratory for quality control for specialized work should prove beneficial. It was noted that the participant from the United Arab Republic indicated that his country would be willing to offer its facilities towards the establishment of such a reference laboratory and that the participant from Pakistan indicated that his country might possibly do likewise;

b) such a reference laboratory would also serve as a training centre in pharmaceutical quality control, for qualified personnel from different countries;

c) in the interim period, it is hoped that well equipped official control laboratories will offer their facilities to member countries of the Region requesting assistance for special tests;

III

a) in view of the complexity of the problems facing member countries in the field of quality control, an exchange of information and experience should take place whenever needed between national pharmaceutical quality control laboratories;

b) gross deficiencies in the quality control of imported drugs and pharmaceutical preparations, resulting especially from failure to comply with the specifications in the quality of imported drugs and pharmaceutical preparations which may result in medical hazards to the users by substantially reducing the potency or enhancing the toxicity should, preferably after verifying the conclusions by another competent laboratory, be communicated confidentially by the highest authority for health to its counterpart in the other member countries of the Region, and to WHO and to the exporting country;

IV

the WHO certification scheme recommended in Resolution WHA/22/50 for adoption and application by Member States, could be extremely helpful to member countries as soon as effective and complete administrative procedures for implementation of the scheme are developed. It was stressed, however, that even when such a certificate is made available it could not act as a substitute for official quality control;

V

In view of the importance of quality control during manufacture, member countries, when adopting and implementing Good Practices in the Manufacture and Quality Control of Drugs recommended in the above mentioned Resolution should foster and facilitate the installation of adequately equipped quality control laboratories in the pharmaceutical manufacturing establishments;

VI

in view of the importance of effectively supervising all steps, from purchase of raw materials to manufacturing, storage and distribution of drugs and medicines, an adequate Division of Pharmacy and Medical Supplies should be established in every Ministry of Health. It should be under the direction of a suitably qualified pharmacist directly responsible to the most senior officer in the department of health;

VII

it is essential that every country in the Region should include in its legislation a clear provision to make mandatory the disclosure of the formula on the container of any pharmaceutical product and on its package;

VIII

short courses for the training of qualified pharmacists as inspectors of pharmaceutical establishments are required at the regional or inter-regional level in order to attain the required standard of inspection of pharmacies and pharmaceutical manufacturing establishments;

IX

In view of the benefits to the Region resulting from this Seminar, similar technical meetings on pharmaceutical quality control should be organized in the future, as soon as possible. This is particularly necessary in order to keep up with the continuous introduction into therapeutics of new and more potent pharmaceutical preparations imported or locally manufactured and with the use of new techniques in pharmaceutical quality control.

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Miss P. Cartoudis	Conference Officer	WHO Regional Office for the Eastern Mediterranean

AGENDA

I Opening of the Travelling Seminar

II Election of Officers and adoption of the Agenda

III Introduction

IV Pharmaceutical quality control in countries of the Region

V Registration of pharmaceutical specialities

VI Principles for pharmaceutical quality control

VII Control directions and records in pharmaceutical manufacturing establishments

1. WHO requirements for good manufacturing practice in the production and quality control of drugs and pharmaceutical specialities and their applications

2. Pharmaceutical preparations in medical stores a) stored b) manufactured at medical stores

3. Stability of pharmaceutical preparations

VIII Pharmaceutical inspection

1. Inspection of pharmaceutical manufacturing establishments

2. Inspection of a) medical stores and of b) pharmacies

3. Training of inspectors

IX National laboratories for pharmaceutical quality control

1. Facilities, equipment, organization of work, personnel

2. Training of a) personnel and b) technical assistants

3. Laboratories for pharmaceutical quality control as an independent unit of central public health laboratory services

X Specifications for pharmaceutical quality control

1. Specifications proposed by WHO

2. Reference chemical and biological substances

3. Specifications from the manufacturer

XI Certification of the quality of pharmaceutical preparations a) imported b) exported

XII Pharmaceutical legislation

XIII Brief review of National Pharmaceutical Services

XIV Field visits

XV Summary report and recommendations

XVI Closing of the Travelling Seminar

PROGRAMME OF THE SEMINAR

SUNDAY 8 March 1970	- Arrival to Islamabad
MONDAY 9 March 1970	- NATIONAL HEALTH LABORATORIES, ISLAMABAD
9:30 a.m.	- Registration of Participants
10:00 a.m.	- Opening Session
	- Inaugural address by H.E. A.K.M. Hafizuddin Minister of Industries and Natural Resources Representative of the Government of Pakistan
	- Message by Dr. A.H. Taba, WHO Director Eastern Mediterranean Region.
10:30 a.m.	- Recess
11:00 a.m.	- Election of Officers, a Chairman, two Vice-Chairmen and Rapporteur
	- Adoption of the Agenda
	- Programme of work
11:15 a.m.	- Introduction and Objectives of the Seminar by Mr. F.S. Bisharah Doct./4
11:20 a.m.	- Pharmaceutical quality control in countries of the Region Reports from countries participating Doct./5

MONDAY 9 March 1970 (cont'd) — ISLAMABAD

3:00 p.m. - Registration of Pharmaceutical Specialities
1. by Mr. P. Blanc — Doct./6a
2. by Dr. A. Naderi, Iran — Doct./6b
3. by Dr. F. Stephan, Lebanon — Doct./6c

3:30 p.m. - Impact of Drug Legislation on Drug Research in Developing Countries
by Professor I. Khan, Pakistan — Doct./7

4:00 p.m. - Principles of Pharmaceutical Quality Control
by Mr. R.I. Samsom — Doct./8

4:30 p.m. - Recess

4:45 p.m. - Manufacturing Control and Records
by Mr. J.W. Lightbown — Doct./9

5:15 p.m. - Quality Control of Pharmaceutical Forms
by Professor A.H. Beckett — Doct./10

5:45 p.m. - Slides on: "Application of strict principles of good manufacturing practices"

TUESDAY 10 March 1970 — ISLAMABAD

8:30 a.m. - Steering Committee

9:00 a.m. - Stability of Pharmaceutical Preparations
by Professor A.H. Beckett — Doct./11

9:30 a.m. - Inspection of Pharmaceutical Manufacturing Establishments
1. by Mr. R.J. Samsom — Doct./12a
2. by Dr. G.M. Junejo, Pakistan — Doct./12b

10:00 a.m. - Training of Expert Staff for the Quality Control of Pharmaceutical Preparations
by Professor A.F. Haddad — Doct./13

10:30 a.m. - Recess

10:45 a.m. - Quality Control of Antibiotics
by Mr. J.W. Lightbown — Doct./14

TUESDAY 10 March 1970 (cont'd)	ISLAMABAD	
11:15 a.m.	- National Laboratories for Pharmaceutical Quality Control	
	1. by Dr. H. Sabart	Doct./15a
	2. by Dr. A. Rafizadeh, Iran	Doct./15b
11:45 a.m.	- National Laboratories for Pharmaceutical Quality Control, Independent Unit of the Central Public Health Laboratory Services	
	by Dr. H.R. Husseini	Doct./16
12:15 p.m.	- Specifications proposed by WHO Document	
	by Mr. O. Wallen	Doct./17a
3:00 p.m.	- Visit to the various sections of the National Health Laboratories, Islamabad	
4:45 p.m.	- Recess	
5:00 p.m.	- Movie Film: "Modern Medicine"	
WEDNESDAY 11 March 1970	ISLAMABAD	
8:30 a.m.	- Steering Committee	
9:00 a.m.	- Specifications and Analytical Information Obtained from the Pharmaceutical Manufacturer	
	by Dr. H. Sabart	Doct./17b
9:30 a.m.	- Certification of Imported Pharmaceutical Preparations	
	1. by Mr. O. Wallen	Doct./18a
	2. by Mr. A.H. Ibrahim, Sudan	Doct./18b
10:30 a.m.	- Recess	
10:45 a.m.	- Pharmaceutical Legislation	
	1. by Mr. P. Blanc	Doct./19a
	2. by Participant from U.A.R.	Doct./19b
11:15 a.m.	- National Pharmaceutical Services as applied to Quality Control	
	1. by Mr. F.S. Bisharah	Doct./20a
	2. by Mr. A.R. Rawabdeh, Jordan	Doct./20b

WEDNESDAY 11 March 1970 (cont'd)	ISLAMABAD
3:00 p.m.	- Panel Discussion: "Pharmaceutical Quality Control as part of Public Health Services" Members of the Panel: Mr. P. Blanc Professor I. Khan Professor A. Haddad Professor A.H. Beckett Mr. R.J. Samsom Mr. J.W. Lightbown
THURSDAY 12 March 1970	ISLAMABAD
8:30 a.m.	- Closing Session of Part of the Seminar ending in Islamabad
9:30 a.m.	- Travel from Rawalpindi to Lahore
	LAHORE
11:00 a.m.	- Visit to Punjab Pharmacies
8:25 p.m.	- Travel from Lahore to Karachi
FRIDAY 13 March 1970	KARACHI
9:00 a.m. - 12:00	- Visit to Jinnah Post-Graduate Medical Centre
2:30 p.m. - 5:00 p.m.	- Visit to Glaxo Laboratories
SATURDAY 14 March 1970	KARACHI
9:00 a.m. - 12:00	- Visit to Pakistan Pharmaceutical Products
2:30 p.m. - 5:00 p.m.	- Visit to Eastern Pharmaceutical Laboratory
SUNDAY 15 March 1970	
7:30 a.m.	- Travel from Karachi to Teheran

MONDAY 16 March 1970	TEHERAN
9:00 a.m.	- Meeting at the Ministry of Public Health Address by H.E. Dr. M. Shahgholi, Minister of Health
10:00 a.m.	- Visit to Pharmaceutical House Daru Pakhsh
3:00 p.m.	- Other field visits
TUESDAY 17 March 1970	TEHERAN
9:00 a.m.	- Visit to Government Laboratory for Quality Control at Nijad Hospital
10:00 a.m.	- Visit to Pharmaceutical House Toli Daru
3:00 p.m.	- Other field visits
WEDNESDAY 18 March 1970	
8:15 a.m.	- Travel from Teheran to Cairo
THURSDAY 19 March 1970	CAIRO
9:30 a.m.	- Meeting with H.E. The Minister of Health of the United Arab Republic and with the WHO Regional Director
11:00 a.m.	- Visit to the Drug Research and Control Centre
12:00 noon	- Visit to the Nile Pharmaceutical Co.
SATURDAY 21 March 1970	CAIRO
9:00 a.m.	- Closing Session of the Travelling Seminar at the Drug Research and Control Centre
10:00 a.m.	- Visit to El Nasr Pharmaceutical Chemicals Co.
	- Summary of Conclusions and Recommendations.

LIST OF BASIC DOCUMENTS

AGENDA	EM/SEM.QUAL.CTR.PHARM/1
PROGRAMME OF THE SEMINAR	EM/SEM.QUAL.CTR.PHARM/2
LIST OF PARTICIPANTS AND OBSERVERS	EM/SEM.QUAL.CTR.PHARM/3
INTRODUCTION AND OBJECTIVES OF THE SEMINAR by Mr. F.S. Bisharah Regional Adviser on Pharmacy and Medical Supplies	EM/SEM.QUAL.CTR.PHARM/4
PHARMACEUTICAL QUALITY CONTROL IN COUNTRIES OF THE REGION Reports from countries participating	EM/SEM.QUAL.CTR.PHARM/5
REGISTRATION OF PHARMACEUTICAL SPECIALITIES by Mr. P. Blanc WHO Consultant	EM/SEM.QUAL.CTR.PHARM/6a
Dr. A. Naderi Supervisor, General Department for Pharmaceutical Affairs Ministry of Public Health, Teheran	EM/SEM.QUAL.CTR.PHARM/6b
Dr. F. Stephan Head of the Chemistry Section Central Laboratory of Public Health Ministry of Public Health, Beirut	EM/SEM.QUAL.CTR.PHARM/6c
IMPACT OF DRUG LEGISLATION ON DRUG RESEARCH IN DEVELOPING COUNTRIES by Professor I. Khan Director, Drugs Research Institute, Islamabad	EM/SEM.QUAL.CTR.PHARM/7
PRINCIPLES OF PHARMACEUTICAL QUALITY CONTROL by Mr. R.J. Samsom Director of Public Health for Drugs Ministry of Social Affairs and Public Health, Leidschendam, Netherlands	EM/SEM.QUAL.CTR.PHARM/8

MANUFACTURING CONTROL AND RECORDS
by Mr. J.W. Lightbown
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QUALITY CONTROL OF PHARMACEUTICAL FORMS
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STABILITY OF PHARMACEUTICAL PREPARATIONS
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INSPECTION OF PHARMACEUTICAL MANUFACTURING ESTABLISHMENTS
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TRAINING OF EXPERT STAFF FOR THE QUALITY CONTROL OF PHARMACEUTICAL PREPARATIONS
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NATIONAL LABORATORIES FOR PHARMACEUTICAL QUALITY CONTROL
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SPECIFICATIONS PROPOSED BY WHO DOCUMENT
by Mr. O. Wallen
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SPECIFICATIONS AND ANALYTICAL INFORMATION OBTAINED FROM THE PHARMACEUTICAL MANUFACTURER
by Dr. H. Sabart
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CERTIFICATION OF IMPORTED PHARMACEUTICAL PREPARATIONS
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Amman — EM/SEM.QUAL.CTR.PHARM/20b

LIST OF BACKGROUND DOCUMENTS

1.	WHO Resolution	WHA 21.37
2.	Report of a Study on Use of Specifications for Pharmaceutical Preparations (WHO Technical Report Series)	No.138
3.	Report on a European Technical Meeting on the Quality Control of Pharmaceutical Preparations (WHO Technical Report Series)	No.249
4.	Twenty-First Report of WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series)	No.307
5.	Lists of Proposed International Non-Proprietary Names for Pharmaceutical Preparations	Cumulative List No.2, 1967 (List 1-17) & (18-21)
6.	WHO Draft Requirements for Good Manufacturing Practice in the Manufacture and Quality Control of Drugs and Pharmaceutical Specialities	WHO/Pharm/67.444
7.	WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series)	No.418
8.	Specifications for the Quality Control of Pharmaceutical Preparations (International Pharmacopoeia - Second Edition)	
9.	Specifications for Reagents mentioned in the International Pharmacopoeia	
10.	Report of a WHO Scientific Group on Principles for Pre-Clinical Testing of Drug Safety (WHO Technical Report Series)	No.341
11.	Distribution of and Trade in Pharmaceutical Preparations - A survey of Existing Legislation - WHO, Geneva, 1962	
12.	Twentieth Report of WHO Expert Committee on Biological Standardization (WHO Technical Report Series)	

13.	WHO Resolution	WHA22.50
14.	WHO Resolution	WHA22.54
15.	Report by the Director General on "Quality Control of Drugs", Twenty-Second World Health Assembly	A22/P&B/12
16.	Report of a Visit to Cyprus by Dr. H. Davis, WHO Consultant, 1967	EM/PHARM/24
17.	Report of a Visit to Iran by Mr. P. Blanc, WHO Consultant, 1968	EM/PHARM/26
18.	Report of a Visit to Sudan by Mr. F.S. Bisharah, WHO Regional Adviser on Pharmacy and Medical Supplies, 1969	EM/PHARM/29
19.	Report of a Visit to Jordan by Mr. O.G. Pederson, WHO Consultant, 1969	EM/PHARM/30
20.	Report of a Visit to the People's Republic of Southern Yemen by Mr. F.S. Bisharah WHO Regional Adviser on Pharmacy and Medical Supplies, 1969	EM/PHARM/31