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**EXPERT COMMITTEE  
ON THE UNIFICATION  
OF PHARMACOPOEIAS**

**Report on the Sixth Session**

*New York City, N.Y., 20-29 April 1950*

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WORLD HEALTH ORGANIZATION

PALAIS DES NATIONS

GENEVA

OCTOBER 1950

**EXPERT COMMITTEE ON THE UNIFICATION  
OF PHARMACOPOEIAS**

**Sixth Session**

*Members :*

- Dr H. Baggesgaard-Rasmussen, Professor of Pharmaceutical Chemistry, Danish School of Pharmacy, Copenhagen, Denmark; Member of the Danish Pharmacopoeia Commission
- Professor E. Fullerton Cook, Pharm.D., Chairman, Committee of Revision of the Pharmacopoeia of the United States of America, New York City, N.Y., USA (*Vice-Chairman*)
- Dr I. R. Fahmy, Professor of Pharmacognosy, Fouad I University, Cairo, Egypt; Secretary, Egyptian Pharmacopoeia Commission
- Dr H. Flück, Professeur de Pharmacognosie à l'Ecole Polytechnique Fédérale, Zürich, Switzerland; Membre de la Commission fédérale de la Pharmacopée
- Dr C. H. Hampshire, Secretary, British Pharmacopoeia Commission, General Medical Council Office, London, United Kingdom (*Chairman*)
- Dr R. Hazard, Professeur de Pharmacologie et de Matière médicale à la Faculté de Médecine de l'Université de Paris, France; Membre de la Commission permanente du Codex
- Dr D. van Os, Professor of Pharmaceutical Chemistry and Toxicology, University of Groningen, Netherlands; Chairman, Netherlands Pharmacopoeia Commission

*Co-opted Members :*

- Dr D. Mayoral Pardo, Professor of Pharmacology and Therapeutics, Faculty of Medicine, National University of Mexico, and at the Military Medical School, Mexico D.F., Mexico; Chairman, Committee of Revision of the Mexican Pharmacopoeia
- Dr C. A. Morrell, Director, Food and Drugs Division, Department of National Health and Welfare, Ottawa, Canada; Chairman, Canadian Committee on Pharmacopoeial Standards

*Representative of the United Nations :*

- C. Fulton, Division of Narcotic Drugs, Department of Social Affairs, Lake Success, N.Y.

*Observers :*

- Dr L. Miller, Director-Elect, Committee of Revision of the Pharmacopoeia of the United States of America, New York City, N.Y., USA
- T. Rosin, Ph.M., Member of the Committee of Revision of the Pharmacopoeia of the United States of America, New York City, N.Y., USA
- Dr R. I. Stormont, Secretary, Council on Pharmacy and Chemistry, American Medical Association, Chicago, Ill., USA

*Secretary :*

- P. Blanc, Chief, Pharmaceutical Section, WHO

The report on the sixth session of this committee was originally issued in mimeographed form as documents WHO/Pharm/96, 29 April 1950, and WHO/Pharm/96 Rev. 1, 25 May 1950.

# EXPERT COMMITTEE ON THE UNIFICATION OF PHARMACOPOEIAS

## Report on the Sixth Session<sup>1</sup>

The Expert Committee on the Unification of Pharmacopoeias held its sixth session at the US Pharmacopoeial Building, 46 Park Avenue, New York City, N.Y., from 20 to 29 April 1950.

### 1. Publication of the First Edition (Editio Prima) of the Pharmacopoea Internationalis (Ph.I.)

The committee noted that the Executive Board, at its fifth session, had adopted the report on the fifth session of the Expert Committee on the Unification of Pharmacopoeias.<sup>2</sup> In accordance with Article 23 of the Constitution of WHO, the Ph.I. will be sent to member countries with the following recommendation :

The Third World Health Assembly

- (1) APPROVES of the *Pharmacopoea Internationalis* ; and
- (2) RECOMMENDS the eventual inclusion of its provisions in the national pharmacopoeias after the adoption of the said provisions by the authorities responsible for the pharmacopoeias.<sup>3</sup>

The members outlined the probable attitude of their respective countries with regard to the *Pharmacopoea Internationalis*. Canada had no national pharmacopoeia and therefore recognized those of other countries as

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<sup>1</sup> The Executive Board, at its sixth session, adopted the following resolution:  
The Executive Board

1. NOTES the report on the proceedings of the sixth session of the Expert Committee on the Unification of Pharmacopoeias, and
2. AUTHORIZES its publication ;  
(*Off. Rec. World Hlth Org.* 29)

<sup>2</sup> *Off. Rec. World Hlth Org.* 25, 7

<sup>3</sup> *Off. Rec. World Hlth Org.* 25, 7 ; see also *Off. Rec. World Hlth Org.* 28, resolution WHA3.10.

standard authority and, when these were unsuitable for certain drugs, set up certain standards under the Food and Drugs Act. However, this was not found altogether practical and a Canadian Pharmacopoeia was therefore under consideration. It was likely that the Ph.I. would serve as a basis in the preparation of the Canadian Pharmacopoeia. The second edition of the national Mexican Pharmacopoeia had just been printed, but the standards of the Ph.I. would probably be adopted in future editions. The Netherlands had already adopted the titles of the Ph.I., and would adopt its standards so far as possible. Egypt would adopt the titles and standards of the Ph.I. in its edition now under press. Denmark had already published a recent edition of its Pharmacopoeia, and the titles and the standards of the Ph.I. would be adopted wherever possible in the addendum under preparation. The Pharmacopoeia of the United States of America (USP) would adopt the titles of the Ph.I. as synonyms or as titles, except when the titles were registered as trademarks. The USP would doubtless continue its policy of using international reference standards as far as applicable. In Switzerland the tendency was to adopt the titles and standards of the Ph.I. for the edition of its Pharmacopoeia now under preparation; some titles and standards had been adopted for the second supplement. France would endeavour to incorporate as many monographs as possible in the next edition of the French Codex, as well as the standards. The next edition of the British Pharmacopoeia would be prepared in accordance with the Ph.I., with the reservation that modifications in detail would be made.

The committee noted that the Ph.I., when approved by the Third World Health Assembly, to be held at Geneva in May 1950, would be sent, after publication, to governments to be transmitted by them to their pharmacopoeial commissions.

#### 1.1 *Biological standards in the Ph.I.*

The committee noted that the Executive Board had recommended to the Third Health Assembly the adoption of international biological standards and units.<sup>4</sup> These had now been incorporated in the Ph.I. for all drugs for which a biological assay was required.

#### 1.2 *English edition*

The committee noted that at the time of its last session a large number of monographs and many appendices had already been printed in galley proofs. It had then been decided to leave to the Chairman the task of incorporating the comments which had not been considered during the

<sup>4</sup> *Off. Rec. World Hlth Org.* 25, 7

session for lack of time.<sup>5</sup> As a result of the work he had accomplished, together with other members of the committee, the English text was now complete. It had been necessary to print second galley proofs because of the many changes made by the members since the printing of the first galley proofs. A hundred monographs were now in second galley proofs and it was expected that all would be in second galley proofs by the end of May, so that page proofs, including structural formulae, could be printed. Page proofs would then be submitted to the members before final publication. The volume would be published on the general plan of national pharmacopoeias, with a preface, general notices, monographs and appendices, a general index, and an index of Latin names of the drugs.

### 1.3 *French edition*

It was unanimously agreed that, unless too much time were to elapse before the final French text was completed, it would be desirable to delay the final English edition so that the two editions could be published simultaneously. The help of Professeur Hazard in the preparation of the French text was gratefully acknowledged.

### 1.4 *Spanish edition*

Following the publication of the Ph.I. in French and in English, a Spanish translation will be published. The committee noted that the matter had been taken up with the Division of Editorial and Reference Services, and that an experienced translator had been proposed to undertake the translation. Dr Mayoral Pardo agreed to assist in an advisory capacity in the preparation of the Spanish text of the Ph.I.

### 1.5 *List of synonyms*

The committee noted the list of synonyms for the drugs which are to be included in the first edition of the Ph.I. and in the Addendum, and recommended that it should be circulated among the members for their comments and additions. The committee considered that the Legal Office of WHO should investigate the situation with regard to US patent laws which might prevent the use of any trademarks registered in the USA unless the name of the manufacturer were mentioned at the same time.

### 1.6 *Preface*

The committee considered the draft preface, and recommended its incorporation in the first edition of the Ph.I.

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<sup>5</sup> *World Hlth Org. techn. Rep. Ser.* 1950, **12**, 4

## 2. International Secretariat for Pharmacopoeias

The committee adopted the following resolution :

The Expert Committee on the Unification of Pharmacopoeias  
RECOMMENDS that the International Secretariat for Pharmacopoeias be placed exclusively under the aegis of the World Health Organization, as recommended at the fourth session of the expert committee.<sup>161</sup>

## 3. Agreement Revising the Agreement Respecting the Unification of Pharmacopoeial Formulas for Potent Drugs, Signed at Brussels, August 20, 1929

The committee adopted the following resolution :

The Expert Committee on the Unification of Pharmacopoeias  
RECOMMENDS that the Director-General of the World Health Organization consider the legal standing of the "Agreement Revising the Agreement Respecting the Unification of Pharmacopoeial Formulas for Potent Drugs. Signed at Brussels, August 20, 1929", after the *Pharmacopoea Internationalis* has been published.

## 4. Relations with Other Organizations

The committee adopted the following resolutions :

### I. The Expert Committee on the Unification of Pharmacopoeias

NOTES with satisfaction that the Executive Board has approved the establishment of official relations between the World Health Organization and the International Pharmaceutical Federation.<sup>171</sup>

### II. The Expert Committee on the Unification of Pharmacopoeias

RECOMMENDS that the present system of submitting to other expert committees draft monographs for their comments be continued, as well as the relations established with other medical and scientific international and national organizations working in related fields.

Such relations had been established by WHO and this was of great help in obtaining recognition of the first edition of the Ph.I.

<sup>6</sup> *World Hlth Org. techn. Rep. Ser.* 1950, 1, 4

<sup>7</sup> *Off. Rec. World Hlth Org.* 25, 18

#### 4.1 *International Union of Chemistry*

The correspondence exchanged with the International Union of Chemistry was reviewed and the committee noted that all graphic and chemical formulae of the Ph.I. had been approved by the Union. The standards for reagents to be used in the Ph.I. were to be established in collaboration with the Union. The Union had mentioned that it might take considerable time for them to establish these standards. It was agreed that, should the delay be too long, the committee could prepare standards for reagents and would refer to the new standards published by the American Chemical Society and to the standards for reagents indicated in national pharmacopoeias. It was agreed that contact would be maintained with the Union's Committee for Standardizing the Purity of Chemical Products, and that Professor van Os would keep WHO informed about the work of that Committee. The committee noted that the Appendix on powders and sieves had been prepared, taking into consideration information received from the International Organization for Standardization (ISO).

#### 4.2 *World Medical Association*

The committee noted the correspondence exchanged with the World Medical Association, referring to names of drugs in the Ph.I. and to the table of doses. Careful consideration was given to the suggestion for changes, and the committee expressed its thanks for the comments received from the Association.

### 5. Relations with Other WHO Expert Committees

#### 5.1 *Expert Committee on Malaria*

The committee noted the correspondence exchanged with the Secretary of the Expert Committee on Malaria, concerning Chlorophenothanum (DDT) and proposing the inclusion of Amodiaquini Hydrochloridum in the Addendum. The committee recommended that the monograph on Chlorophenothanum should be referred to the Expert Committee on Insecticides for its comments. A draft monograph on Amodiaquini Hydrochloridum will be prepared.

#### 5.2 *Expert Committee on Drugs Liable to Produce Addiction*

The committee noted that approval had been given by the Expert Committee on Drugs Liable to Produce Addiction, at its second session, of the principles established by the Expert Committee on the Unification of Pharmacopoeias for the introduction of non-proprietary names.<sup>8</sup>

<sup>8</sup> *World Hlth Org. techn. Rep. Ser.* 1950, 21, 3

### 5.3 *Expert Committee on Venereal Infections*

The committee considered those drugs proposed by the Expert Committee on Venereal Infections, at its third session, for inclusion in the Addendum to the Ph.I.<sup>9</sup> which had not yet been included in the Ph.I. or approved for inclusion in the Addendum. A draft monograph on Procainum et Penicillinum in Oleo cum Alumini Monostearate and a draft monograph on Injunctio Aquosa Procaini et Penicillini will be prepared.

### 5.4 *Expert Committee on Antibiotics*

The committee noted the comments received on the draft monographs on Penicillinum G Kalicum, Penicillinum G Natricum, and Streptomycinum.

### 5.5 *Expert Committee on Tuberculosis*

Consideration was given to the suggestions received, and it was agreed to draft monographs on Acidum Para-Aminosalicylicum and Natrii Para-Amino Salicylas.

### 5.6 *Expert Committee on Biological Standardization*

The committee noted the comments submitted by members of the Expert Committee on Biological Standardization on the texts of the monographs and appendices of drugs requiring biological standardization. These comments had been forwarded to Dr A. A. Miles of the National Institute for Medical Research, London, acting for the Chairman of that committee, who had revised the texts.

## 6. Addendum to the Ph.I.

The greater part of the session was devoted to consideration of the draft monographs and reports for the preparation of the first Addendum. One hundred and fifty-one monographs and appendices had been prepared by the members for consideration by the committee (see the list in Annex 2).<sup>10</sup>

### 6.1 *Basic substances*

The following draft monographs were accepted with amendments: Oxyconi Hydrochloridum, Hydroconi Bitartras, Dihydromorphinoni Hydrochloridum, Propylthiouracilum, Thyroidea, and Digitoxosidum.

<sup>9</sup> *World Hlth Org. techn. Rep. Ser.* 1950, 13, 18

<sup>10</sup> See page 18.

Digitoxosidum gave rise to the question of pure reference standard substances, because of the colorimetric assay it contained. It also included a biological test, and it was decided to refer this monograph to the Expert Committee on Biological Standardization. The committee also agreed to refer to that committee the question of the establishment and distribution of chemical reference standards. A draft monograph on Suraminum Natricum containing a test for toxicity was also referred to the Expert Committee on Biological Standardization. Penicillinum G Natricum, Penicillinum G Kalicum, and Streptomycinum were discussed and new draft monographs will be prepared. It was agreed that the name Benzylpenicillinum should be adopted.

### 6.2 *Injections*

In preparing the text for a general article on injections, attention was given to the fact that the preparation of sterile injections should be made possible in pharmacies as well as in larger manufacturing firms. The committee decided to refer the text on the pyrogen test and the tests for sterility to the Expert Committee on Biological Standardization. A sterility test will be required for each injectable preparation.

The committee recommended that methods of sterilization be given in each monograph. The autoclave and the filtration will be recommended as the two principal methods of sterilization. For certain thermolabile substances, heating after addition of a bactericide will be approved. A special statement will indicate that certain methods of sterilization which cannot guarantee sterility are to be condemned, e.g., tyndallization, or heating in flowing steam without the addition of bacteriostatic substances. Thermostability and thermolability of the drugs used in the preparation of sterile injections were discussed and decisions were taken. Only a limited number of monographs could be considered in the short time available, and the final preparation of the other monographs on injections was left to the Chairman and WHO, to be completed on the principles established by the committee.

The following draft monographs on injections were considered : *Injectio Aminophyllini*, *Injectio Calcii Gluconatis*, *Injectio Carbacholi*, *Injectio Coffeini et Natrii Benzoatis*, *Injectio Dextrosi*, *Injectio Emetini Hydrochloridi*, *Injectio Ergometrini Maleatis*, *Injectio Morphini Hydrochloridi*, *Injectio Neostigmini Methylsulfatis*, *Injectio Ouabaini*, *Injectio Phenobarbitali Natrici*, and *Injectio Procaini Hydrochloridi*.

### 6.3 *Tablets*

The committee recommended that tablets for internal use and tablets for the preparation of solutions for external use should be differentiated by

their shape. It was agreed that a table indicating the limits of variability of the labelled amount allowed for each strength of tablet should be included in the draft of the general article on tablets. A table, as contained in the British Pharmacopoeia (BP), indicating the margin of tolerance according to the number of tablets available for analysis should be included. It was agreed that a draft article on tablets would be prepared.

The following draft monographs were considered by the committee and accepted with amendments: Compressi Acidi Acetylsalicylici, Compressi Amidopyrini, Compressi Aminophyllini, Compressi Amphetamini Sulfatis, Compressi Barbitali, Compressi Barbitali Natrici, Compressi Calcii Gluconatis, Compressi Calcii Lactatis, Compressi Carbacholi, Compressi Carbarsoni, Compressi Chionofoni, Compressi Codeini Phosphatis, Compressi Colchicini, Compressi Dicoumaroli, Compressi Digitalis, Compressi Ephedrini Hydrochloridi, Compressi Ergometrini Maleatis, Compressi Ergotamini Tartratis, Compressi Extracti Cascarae Sagradae, Compressi Ferrosi Sulfatis, Compressi Glyceryli Trinitratis, Compressi Mepacriini Hydrochloridi, Compressi Hydrargyri Subchloridi, and Compressi Phenacetini.

The revision of the other monographs on tablets was left to the Chairman and WHO, to be made on the basis of the comments submitted by the members on the monographs reviewed during the session.

Consideration was also given to the possible methods of analysing the active principles of coated tablets. A report indicating a method for the removal of the coating and information on the analysis of coated tablets will be prepared for consideration at the next session of the committee.

#### 6.4 *Table of posology for children*<sup>11</sup>

The committee considered the table giving usual doses of drugs for children, and the introduction to the table. The committee wished to stress the fact that these doses should serve as a general indication only, the physician retaining complete freedom in establishing individual doses in his prescriptions. It was agreed that the members would seek the advice of the specialists of their pharmacopoeial commissions and other prominent paediatricians in their countries, and that the table should also be submitted to the World Medical Association and to the WHO Expert Committee on Maternal and Child Health for comments. Professeur Hazard agreed to take these comments into account in preparing another draft of the introduction to the table.

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<sup>11</sup> Unpublished working document WHO/Pharm/93

### 6.5 *New methods of analysis*

The committee agreed to consider at its next session new analytical methods for the testing and assaying of drugs—such as chromatography, colorimetry with matching fluids, polarography, and spectrophotometry—for later addenda to the Ph.I. A working party, headed by Professor Baggesgaard-Rasmussen, with Professors Flück, Hazard, and van Os as members, agreed to prepare reports for consideration at the next session of the committee. In the case of equal accuracy, the simpler method or methods requiring use of existing equipment, would be preferable.

## 7. Non-Proprietary Names<sup>12</sup>

The committee noted that the Executive Board, at its fifth session, had recommended to the Third Health Assembly the adoption of the principles for the introduction of non-proprietary (generic) names for drugs, in order to avoid the difficulties arising from a multiplicity of names for the same medicinal substance.<sup>13</sup> The Director-General of WHO, in a letter sent 13 March 1950, had asked the opinion of Member States on these

<sup>12</sup> The Executive Board, at its sixth session, adopted the following resolution :

The Executive Board...

#### 4. RECOMMENDS

(1) that national pharmacopoeial authorities or other bodies dealing with the establishment of non-proprietary names in the different countries should indicate to WHO new drugs which might be described in the *Pharmacopoea Internationalis* and for which a non-proprietary name should be given for national and international use ;

(2) that national pharmacopoeial authorities, national public-health administrations, or national drug administrations or similar bodies, invite manufacturers and research laboratories to indicate to them, or with the concurrence of the first named authorities direct to WHO, new drugs mentioned in paragraph (1) above, these indications being sent to WHO with or without suggestions for names ;

(3) that members of the committee be invited to submit similar indications direct to WHO ;

(4) that a subcommittee of three members of the expert committee be set up to decide in collaboration with WHO on the name to be selected ;

(5) that names decided upon be then communicated by WHO to its Member States, to members of the committee, and to the authorities mentioned in paragraph (2) above, with the recommendation that they should be adopted for national use, in accordance with the procedure set forth in the recommendation adopted by the Third World Health Assembly ;

(6) that when there is an objection to the adoption of the name decided upon — if, for instance, the proposed name or a closely similar name is already registered as a trademark in a country — a name as similar as possible to the name decided upon and respecting the general principles for a system of international non-proprietary names be adopted.

(*Off. Rec. World Hlth Org.* 29)

<sup>13</sup> *Off. Rec. World Hlth Org.* 25, 8

principles. The committee noted that so far full approval of these principles had been received from Iran, the Hashemite Kingdom of the Jordan, Lebanon, New Zealand, Portugal, Syria, the United Kingdom, and the USA.<sup>14</sup>

It was now important to devise a mechanism whereby non-proprietary names could be given rapidly to new drugs for national and international use, if possible before the drug is put on the market. Full collaboration and goodwill from all concerned was essential, as well as speed. A solution to the problem was not easy, but one should be found in order to prevent in the future the creation of a multiplicity of non-proprietary names and the resulting confusion and difficulties in the prescribing and dispensing and in the control of drugs moving in international commerce. The committee considered the various aspects of the problem and the procedure followed in a number of countries. It was the general opinion that no mechanism could operate with complete success, mainly because it was not possible to devise names acceptable in all countries, due to the large number of names already registered as trademarks. However, introduction of a proper mechanism by WHO on the international level would do much to obviate in the future the difficulties resulting at present from the introduction of different names in different countries for the same drug.

The committee invited Dr Stormont, Secretary of the Council on Pharmacy and Chemistry of the American Medical Association, the authority responsible for issuing *New and Non-official Remedies*, to take part in a discussion on the problem. The members explained the position regarding the introduction of non-proprietary names in their respective countries, and Dr Stormont agreed to invite the full collaboration of the Council with WHO in the mechanism recommended by the committee. He would ask the Council, and the firms concerned, if the necessary information concerning drugs which were to be introduced on the market could be given to WHO before a generic name had been decided upon in the USA. The US Food and Drugs Administration should also be asked whether they would furnish WHO with advance information on new drugs presented for clearance by the various firms, in order to allow WHO to devise in advance a name which could have international as well as national recognition. The co-operation of industry was essential. The committee recommended that WHO ask the Food and Drug Administration to give advance information.

Professor Cook agreed to consult with the Joint Contact Committee of the American Drug Manufacturers Association and the American Pharmaceutical Manufacturers' Association, and the Council on Pharmacy and

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<sup>14</sup> By 31 August 1950, replies and comments had been received from 30 Member States.

Chemistry of the American Medical Association in an endeavour to secure their full collaboration in advising WHO of any new products they intended to place on the market so that international names might be established.

The committee adopted the following resolution :

The Expert Committee on the Unification of Pharmacopoeias,

In order to devise a mechanism for the introduction of non-proprietary names for new pharmaceutical products moving in international commerce,

RECOMMENDS

1. that national pharmacopoeial authorities, or other bodies dealing with the establishment of non-proprietary names in the different countries, indicate to the World Health Organization new drugs for which a non-proprietary name should be found for national and international use ;
2. that manufacturers, research laboratories, food and drugs administrations, and members of the committee, be invited to indicate to their national pharmacopoeial authorities or other bodies, or directly to WHO, new drugs which they think could move later in international commerce and to which non-proprietary names should be given : the national pharmacopoeial authorities or other bodies would send these indications with or without suggestions for names to WHO ;
3. that WHO set up a subcommittee of the Expert Committee on the Unification of Pharmacopoeias to advise, in collaboration with WHO, on the names to be selected : the selected names should then be sent to the members of the committee for approval with the least possible delay, time being an essential factor ;
4. that names decided upon be then communicated by WHO to its Member States, and to national pharmacopoeial authorities and other bodies, with the recommendation that they should be adopted for national use in accordance with the procedure set forth in the recommendation proposed for adoption by the Third World Health Assembly ;<sup>[15]</sup>
5. that when there is an objection to the adoption of the name decided upon — if, for instance, the proposed name or a closely similar name is already registered as a trademark in a country — a name as similar as possible to the name decided upon, and respecting the principles for the introduction of non-proprietary names for drugs, be adopted.

<sup>15</sup> See resolution WHA3.11 adopted by the Third World Health Assembly (*Off. Rec. World Hlth Org.* 28)

It was proposed that Dr Hampshire (Chairman), Professor Baggesgaard-Rasmussen, and Professeur Hazard should constitute the sub-committee mentioned in paragraph 3 of the above recommendation.

### 8. Fellowships

The correspondence exchanged on fellowships to be granted to students or graduates for study of problems connected with the establishment of pharmacopoeial standards for drugs and with the control of drugs was reviewed. It had been suggested that three fellowships should be granted for such purposes, primarily to students or graduates from less-developed countries. It was stressed that the intention was primarily to give Fellows such training as would benefit their own countries and governments. The committee agreed to recommend that the Fellow selected should be a member of a national pharmacopoeial commission, or an assistant to a professor, or a government worker dealing with the control of drugs, so that his research would be of general benefit to his country and to the group of which he was a member.

The committee adopted the following resolution :

The Expert Committee on the Unification of Pharmacopoeias

RECOMMENDS that fellowships be granted for a period of two months to a year to pharmaceutical and pharmacopoeial workers in less-developed countries, and that the Fellows be selected with a view

(1) to studying methods used in the preparation of pharmacopoeias ;  
and

(2) to studying the control of drugs in laboratories and by administrations of other countries with a view to assisting in the preparation of the pharmacopoeias of their own countries and in developing unified methods of control of drugs, in order to allow greater freedom in the prescription by physicians and greater safety in the compounding of prescriptions, and in order to facilitate international commerce.

The members gave assurance that their respective countries would welcome WHO Fellows and expressed their willingness to advise on the suitability of any candidate proposed for a fellowship. Due consideration should be given to the knowledge of the language of the country where the Fellow would be sent. The names of a number of laboratories or research centres where Fellows might be sent for training and study were submitted by the committee.

### 9. Control of Drugs<sup>16</sup>

The committee considered the points which should be raised in a questionnaire to be sent by the Director-General of WHO to Member States in order to obtain general information which would be of service to governments, pharmacopoeial authorities, and food and drugs administrations in the various countries.

The committee adopted the following resolution :

The Expert Committee on the Unification of Pharmacopoeias

RECOMMENDS that the following questionnaire be sent to Member States :

1. (a) Is there a national officially recognized pharmacopoeia in your country ?  
(b) If so, when was the last edition published ?  
(c) If there is no national pharmacopoeia, what other pharmacopoeia(s) have official recognition ?  
(d) How is recognition given to the national or other officially recognized pharmacopoeia(s) ?
2. Are there regulations which make the standards in the national or other officially recognized pharmacopoeia(s) enforceable ?  
If so, what are these regulations ?
3. Are there regulations which provide for standards for drugs not included in the pharmacopoeia ?  
If so, what are these regulations ?
4. What are the regulations which control the labelling and advertising of drugs and specialities ?
5. (a) Are the requirements for standards for drugs and specialities and for their labelling and advertising the same for domestic and imported products ? If not, what are the differences ?  
(b) What are the requirements for drugs and specialities manufactured for export ?

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<sup>16</sup> The Executive Board, at its sixth session, adopted the following resolution :  
The Executive Board . . .

3. REQUESTS the Director-General to send to Member States a questionnaire on the lines recommended by the expert committee, in order to obtain general information which would be of service to governments, pharmacopoeial authorities and drug administrations in the various countries ; . . .

(*Off. Rec. World Hlth Org.* 29)

6. Are there regulations controlling the introduction of new drugs and specialities to the market ?
7. What are the regulations for the control and periodical inspection of pharmacies and other places from which drugs are distributed to patients ?
8. (a) What authority is responsible for the enforcement of all the above regulations and requirements ? If more than one authority is responsible, please describe the duties of each.  
(b) What organization has been established by the responsible authority for the enforcement ?  
Has this organization both laboratory and inspection services ?  
(c) How are drugs which do not meet the requirements of the regulations removed from the market, and by what agency is this carried out ?

## Annex 1

PREPARATION OF DRAFT MONOGRAPHS, REPORTS,  
AND EXPERIMENTAL INVESTIGATIONS

Professor Baggesgaard-Rasmussen agreed :

- To prepare draft monographs on : Diphenhydramini Hydrochloridum  
Tripelelennamini Hydrochloridum
- To report on the determination of the volume of injections in containers at 20°C (68°F)
- To report on the analysis of coated tablets (with Professor van Os)
- To prepare drafts on new methods of analysis (with Professors Flück, Hazard, and van Os)

Professor Fullerton Cook agreed :

- To prepare draft monographs on : Bismuthi Potassii Tartras  
Natrii Chloridum
- To provide the assay for Compressi Barbitali

Professor Fahmy agreed :

- To prepare a draft monograph on : Acidum Undecylenicum
- To prepare an article on Compressi

Professeur Flück agreed :

- To report on : Ceto-Bemidonum  
Injectio Calcii Gluconatis  
Injectio Procaini Hydrochloridi  
Melting-range of Hydroconi Hydrochloridum and its oximes  
New methods of analysis

Dr Hampshire agreed :

- To prepare draft monographs on : Injectio Aquosa Procaini et Penicillini  
Procainum et Penicillinum in Oleo cum Alumini Monostearate  
Tubocurarini Chloridum
- To prepare revised draft monographs on : Injectiones

Professeur Hazard agreed :

- To prepare draft monographs on : Aminothiazolum  
Promethazinum
- To re-draft the Table of Usual Doses for Children
- To report on the colorimetric assay of Injectio Procaini Hydrochloridi

Professor van Os agreed :

To prepare draft monographs on : Acidum Para-Aminosalicylicum  
Amodiaquini Hydrochloridum  
Natrii Para-Amino Salicylas

To revise the draft monograph on Natrii Nitras

To report on the analysis of coated tablets (with Professor Baggesgaard-Rasmussen)

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**Annex 2**

**LIST OF DRAFT MONOGRAPHS SUBMITTED BY MEMBERS  
OF THE COMMITTEE FOR INCLUSION IN THE ADDENDUM  
TO THE P.H.I.**

*Draft monographs*

Benzylpenicillinum	Gonadotrophinum Sericum
Chlorophenothanum Medicinale	Isopentaquini Monooxalas (report)
Chlorophenothanum Technicum	Methadoni Hydrochloridum
Dichlorophenarsini Hydrochloridum	Oxophenarsini Hydrochloridum
Digitoxosidum	Penicillinum G Kalicum
Dihydrocodeinoni Tartras Acidus	Penicillinum G Natricum
Dihydromorphinoni Hydrochloridum	Procaini Benzylpenicillinum
Dimercaprolum	Propylthiouracilum
Gonadotrophinum Chorionicum	Streptomycinum
	Suraminum Natricum
	Thyroidea

*Tinctures*

Tinctura Aconiti	Tinctura Ipecacuanhae
Tinctura Belladonnae	Tinctura Scillae
Tinctura Colchici	Tinctura Stramonii
Tinctura Hyoscyami Mutici	Tinctura Strychni

*Injections*

Injectio Adrenalini	Injectio Natrii Morrhuat
Injectio Adrenalini in Oleo	Injectio Natrii Salicylatis
Injectio Aminophyllini	Injectio Neostigmini Methylsulfatis
Injectio Bismuthi Kalii Tartratis	Injectio Nicethamidi
Injectio Calcii Gluconatis	Injectio Oestradioli Benzoatis
Injectio Carbacholi	Injectio Oestroni
Injectio Coffeini et Natrii Benzoatis	Injectio Ouabaini
Injectio Dextrosi	Injectio Papaverini Hydrochloridi
Injectio Diethylstilbestroli	Injectio Pentetrazoli
Injectio Digoxini	Injectio Pethidini Hydrochloridi
Injectio Dihydromorphanoni Hydrochloridi	Injectio Phenobarbitali Natrici
Injectio Dimercapoli	Injectio Picrotoxini
Injectio Emetini Hydrochloridi	Injectio Procaini Hydrochloridi
Injectio Ergometrini Maleatis	Injectio Procaini Hydrochloridi et Adrenalini
Injectio Ergotamini Tartratis	Injectio Progesteroni
Injectio Heparini Natrici	Injectio Stibopheni
Injectio Histamini Phosphatis	Injectio Sulfadiazini Natrici
Injectio Lanatosidi C	Injectio Sulfamerazini Natrici
Injectio Menadioni	Injectio Sulfathiazoli Natrici
Injectio Mersalyli et Theophyllini	Injectio Testosteroni Propionatis
Injectio Morphini Hydrochloridi	Injectio Tubocurarini Chloridi
Injectio Natrii Lactatis	

*Parenteral solutions*

Aqua Pro Iniectione	Solutio Natrii Citratis Anticoagulans
Solutio Acidi Citratis Dextrosi Anticoagulans	Solutio Ringeri
Solutio Natrii Chloridi Isotonica	Solutio Ringeri Lactatus

*Tablets*

Compressi Acidi Acetylsalicylici	Compressi Barbitali Natrici
Compressi Acidi Ascorbici	Compressi Calcii Gluconatis
Compressi Aethisteroni	Compressi Calcii Lactatis
Compressi Aminophyllini	Compressi Carbacholi
Compressi Amphetamini Sulfatis	Compressi Carbarsoni
Compressi Apomorphini Hydrochloridi	Compressi Chionofoni
Compressi Barbitali	Compressi Chloroquini Diphosphatis

*Tablets (continued)*

Compressi Codeini Phosphatis	Compressi Natrii Nitritis
Compressi Colchicini	Compressi Natrii Salicylatis
Compressi Dicoumaroli	Compressi Neostigmini Bromidi
Compressi Diethylstilbestroli	Compressi Nicotinamidi
Compressi Digitalis	Compressi Oestradioli
Compressi Digitoxosidi	Compressi Pethidini Hydrochloridi
Compressi Digoxini	Compressi Phenacetini
Compressi Dihydromorphenoni	Compressi Phenobarbitali
Hydrochloridi	Compressi Phenobarbitali Natrici
Compressi Ephedrini Hydrochloridi	Compressi Phenytoini Natrici
Compressi Ergometrini Maleatis	Compressi Proguanili Hydrochloridi
Compressi Extracti Cascarae Sagradae	Compressi Quinidini Sulfatis
Compressi Ferrosi Sulfatis	Compressi Quinini Sulfatis
Compressi Glyceryli Trinitratis	Compressi Riboflavini
Compressi Hydrargyri Subchloridi	Compressi Santonini
Compressi Hyoscini Hydrobromidi	Compressi Succinylsulfathiazoli
Compressi Lanatosidi C	Compressi Sulfadiazini
Compressi Menadioni	Compressi Sulfaguanidini
Compressi Mepacrini Hydrochloridi	Compressi Sulfamerazini
Compressi Mersalyli et Theophyllini	Compressi Sulfanilamidi
Compressi Methyltestosteroni	Compressi Sulfathiazoli
Compressi Morphini Sulfatis	Compressi Theobromini et Natrii Acetatis
Compressi Natrii Bicarbonatis	Compressi Thiamini Hydrochloridi

*Basic substances*

Acidum Folicum	Natrii Chloridum
Aureomycini Hydrochloridum	Natrii Nitrisi
Bismuthi Kalii Tartras	Quinidini Sulfas
Chloramphenicolum	Tyrothricinum
Dextrosum	Vitaminum B <sub>12</sub>
Dimercaprolum	

*General tests*

Alkali salts of organic acids	Sterility tests for liquids and solids
Requirements for injections	
Pyrogen test	