



SIXTEENTH REPORT

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The Expert Committee on the International Pharmacopoeia met in Geneva from 10-15 November 1958.

1. Participants

Members

\* Professor H. Baggesgaard Rasmussen, Professor of Organic Chemistry, Royal Danish School of Pharmacy, Copenhagen; Member of the Danish Pharmacopoeia Commission and of the Scandinavian Pharmacopoeia Council

Professor A. Calo, General Inspector Chemist, Istituto Superiore di Sanità, Rome; Member of the Italian Pharmacopoeia Commission

Dr T. Canbäck, Director of Chemical Research, Pharmaceutical Control Laboratory, Stockholm; Vice-Chairman of the Swedish Pharmacopoeia Commission; Member of the Scandinavian Pharmacopoeia Council (Chairman)

Mr T. C. Denston, Secretary, British Pharmacopoeia Commission, London (Rapporteur)

Professor J. A. Gautier, Professor of Organic Chemistry, Faculty of Pharmacy, University of Paris, Member of the French Pharmacopoeia Commission

Dr P. H. List, Pharmaceutical Institute, Würzburg University

Dr L. C. Miller, Director of Revision of the Pharmacopoeia of the United States of America, New York (Rapporteur)

Professor P. Senov, Professor of Pharmaceutical Chemistry, Pharmaceutical Faculty, First Medical Institute, Moscow; Chairman of the USSR Pharmacopoeia Commission

Professor S. Suvagondha, Director General, Department of Medical Sciences, Ministry of Public Health, Bangkok (Vice-Chairman)

Secretariat

Mr P. Blanc, Chief, Pharmaceutical Section, Division of Therapeutic Substances (WHO), (Secretary)

Mr G. R. Brown, Scientific Publications Department, Pharmaceutical Society of Great Britain, London (Consultant)

Professor H. Flück, Professor of Pharmacognosy at the Federal Institute of Technology, Zurich; Member of the Federal Pharmacopoeia Commission (Consultant)

Professor R. Hazard, Honorary Professor of Pharmacology and Materia Medica, Faculty of Medicine of Paris University; Member of the French Pharmacopoeia Commission (Consultant)

Dr S. Vinokoureff, Director, Division of Therapeutic Substances (WHO)

Mr O. Wallén, Pharmaceutical Section (WHO)

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\* Unable to attend

## 2. Introduction

The Director of the Division of Therapeutic Substances opened the session by thanking members for their help in submitting in advance proposals for discussion at the meeting. Many documents had been received from members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and other specialists throughout the world as a result of requests from WHO for information, draft texts, criticisms and suggestions, and their co-operation was greatly appreciated. The active participation of many experts, institutes, national laboratories of control and laboratories of pharmaceutical firms in many countries was also much appreciated as it is important that the specifications proposed by WHO for the quality control of pharmaceutical preparations should result from as wide a consultation as possible.

Volumes I and II of the first edition had already been published in English, French and Spanish by WHO, with translations by private firms into German and Japanese. Furthermore, the helpful comments received from the Member States on the text of a Supplement to Volumes I and II had made it possible to advance the text to the galley proof stage. Additional comments submitted recently would be considered and it was hoped to complete the revision of the proofs during the session.

An important part of the agenda of this session would deal with the preparation of a second edition. As a result of the revision, which represents a task of the first magnitude, the I.Ph. will provide authorities concerned with the control of quality of pharmaceutical preparations or the establishment of national pharmacopoeias with the latest recommendations of international experts working under the aegis of WHO. Many articles in professional journals and other information received in correspondence or direct from officials and experts in various countries indicate how this undertaking has filled a great need and is used in many countries as one of the bases for work on the national level.

Reports received from the Centre for Authentic Chemical Substances would be examined and possible additions to the list of substances could be suggested. Further consideration would be given to the programme on information sheets in

keeping with the suggestions made in the fifteenth report of this Expert Committee,<sup>1</sup> and the report of a study group<sup>2</sup> on the use of specifications for pharmaceutical preparations.

### 3. Use of Proposed Specifications

The Secretary and members of the Committee reported that the specifications of the I.Ph. continue to be used extensively in the preparation of specifications for the quality control of pharmaceutical preparations on the national level. A number of national pharmacopoeias have referred to the consideration they have given to these proposed specifications. The Committee noted the resolution adopted at the IV Pan-American Congress of Pharmacy and Biochemistry, held in Washington, November 1957<sup>3</sup> and the resolution adopted at the XVII meeting of the International Pharmaceutical Federation, held in Brussels, September 1958<sup>3</sup> commending the World Health Organization for its work in the field of pharmaceutical preparations.

### 4. Supplement to the First Edition of the International Pharmacopoeia

The Committee noted that drafts of the proposed monographs and appendices intended for inclusion in a Supplement had been circulated to Member States, pharmaceutical and medical associations, members of the Expert Advisory Panel and other specialists, and that the comments received had been examined and integrated in the text for printing, as suggested at the session of the Expert Committee held in October 1957. A number of further comments received from various authorities were examined and appropriate amendments to the text of the galley proofs were approved. Paragraphs on storage were added in order to complete a number of monographs in conformity with the style of volumes I and II.

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<sup>1</sup> WHO/Pharm/330

<sup>2</sup> Wld Hlth Org. techn. Rep. Ser. 168

<sup>3</sup> See Annex 2.

Arrangements were in hand for completing the English and French editions and preparing the Spanish translation of the Supplement which would include monographs. Appendices included in the Supplement would cover such matters as the determination of pH, reagents for carrying out assays by non-aqueous titration, and the generally applicable method of titration of calcium with sodium ethylenediamine tetra-acetate. In this last case the method could be applied as an alternative to the method of assay provided in some of the monographs in volumes I and II of the first edition.

## 5. Reagents

The Committee noted that draft specifications had been made available in roneoed form on all reagents used in the first edition of the I.Ph. These were being submitted for consideration and comment to a number of manufacturers of reagent chemicals. It was recommended that a notice should be inserted in the WHO Chronicle, on the following lines:

"The World Health Organization proposes to publish a volume containing specifications for the reagents required in connexion with the tests described in volumes I and II and the Supplement of the I.Ph. Draft specifications have been prepared with the advice of members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

"A tentative list of these reagents will be supplied on request. Comments on the draft specifications are invited, and copies of the drafts may be obtained for this purpose from the Secretary of the Expert Advisory Panel, on the International Pharmacopoeia and Pharmaceutical Preparations, Palais des Nations, Geneva."

It was expected that comments received could be examined for possible integration by a consultant and that they should be reviewed at the next session of the Expert Committee before being issued as a separate publication.

## 6. Second Edition

The Expert Committee continued the work of preceding sessions on the preparation of a second edition of the I.Ph. The first edition adopted the analytical methods and principles in established use when the first volume was prepared. Some of the newer techniques reported to the Expert Committee and discussed at various sessions, would be included in the second edition. In drafting monographs for the second edition, the Committee now has the opportunity to take full advantage of the improvements in general methods that have been made since the publication of the first edition. Special attention would be given to the needs of lesser developed areas which would require adequate specifications for control of imported and locally manufactured pharmaceutical preparations.

The Expert Committee noted that as a result of work in the Secretariat a number of reports were available summarizing the extensive preparatory work already performed for the second edition. These reports assisted the Expert Committee in establishing some principles for guidance in drawing up the monographs and appendices.

Once the basic plan and general methods have been worked out, monographs can be written according to these principles, but careful laboratory work is essential and subsequent modification of the test may be required to ensure that the specifications are satisfactory. Hitherto it has been possible to obtain the necessary practical trials of the monographs through members of the Expert Advisory Panel and other specialists. Future work is likely to be increasingly complex because of the number of new substances being introduced and of the application of new techniques to the older preparations.

In order that the results of this work may be made available for the second edition, the Expert Committee agreed with the programme suggested by the Secretariat to ask a number of suitable laboratories to co-operate, and agreed that it would be necessary in some cases to provide grants to enable additional staff and equipment to be obtained for this work. The Apotekens Kontrollaboratorium, Stockholm had already stated that it would be willing to carry out work of this kind for WHO and other laboratories, including perhaps two industrial pharmaceutical control

laboratories, could be asked to co-operate. By proceeding in this way, and organizing an interchange of samples between co-operating laboratories, it should be possible to produce specifications of the greatest possible value.

It was agreed that before the proposed monographs were subjected to laboratory examination, the draft text would be reviewed by a working group for the purpose of advising the Secretariat as to the adequacy of the draft specification. Furthermore it was considered essential that arrangements should be made with all the collaborating laboratories before drafts are sent to any of them in order that the requests may be appropriate to the facilities of that laboratory.

6.1 List of contents. The Expert Committee noted that as a result of work in the Secretariat and suggestions by the Expert Committee at earlier sessions, comments and suggestions have been obtained from members of the Expert Advisory Panel and many others. In conformity with the general principles expressed by the Expert Committee in its fifteenth report, a list of proposals for new monographs and also a list of deletions were examined and on this basis a provisional working list of additions and deletions was prepared and is annexed to this report.<sup>1</sup> It is agreed that comments and suggestions should be invited from members of the Expert Advisory Panel, other specialists and national pharmacopoeia commissions on this list. The list would also be submitted to the World Medical Association, the International Pharmaceutical Federation and medical authorities and technical sections within the WHO Secretariat, with a view to obtaining further review and suggestions.

The Secretariat was asked to make a survey of recently published national pharmacopoeias and other volumes of specifications, taking into account provisional lists, to establish what other substances are sufficiently used in the various countries to merit consideration for recognition in the I.Ph.

6.2 Crude drugs. A working group recommended that crude drugs (vegetable and animal) selected should meet the following three criteria: (a) the drug should have a recognized therapeutic activity, (b) a suitable method of assay (chemical, physical or biological) should be available in order that standards may be set up,

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<sup>1</sup> Annex 1.

based on the quality generally available on the market, and (c) the drug should be widely used throughout the world. A working group agreed to submit a list of such drugs to be circulated

6.3 Arrangement of monographs. A number of suggestions from members of the Expert Advisory Panel were considered and it was agreed that the arrangement of the sections of each monograph should follow that used in the first edition, with certain modifications.

6.4 Titles. Titles of the form "Phenobarbital Tablets", "Belladonna Tincture", "Adrenaline Injection", etc. were recommended in place of "Tablets of Phenobarbital" etc. and it was agreed that the text of each monograph should begin with a definition including its title in the language in which the edition is printed.

6.5 Description. A suggestion was considered that the statements made under the heading "Description" should not be regarded as part of the specification but it was agreed that this would be undesirable.

6.6 Solubility. It was agreed that the statements made under the heading "Solubility" should be included for information only and that they should not be regarded as part of the specification unless indicated by special heading, e.g. "Solubility in alcohol".

6.7 General notices. The Expert Committee examined suggestions for the modification of the General Notices included in the first edition and recommended certain changes, including the following: (1) titles in English, French and Spanish, should be regarded as the recommended titles, equivalent to the respective Latin titles; (2) where a substance is defined as being obtained from a specified biological source, synthetic material may be substituted if it is identical in composition.

6.8 Identification tests. It was agreed that an attempt should be made to follow the principle of providing as specific an identification as possible of all substances included in the I.Ph. In some instances, a group reaction might also be included as a rapid means of confirming the class of compound. This would be particularly helpful when other tests could not be applied or in emergencies such as cases of poisoning. Several documents prepared by members of the Expert Advisory Panel and other specialists were examined with a view to improving the existing appendix on general identification tests; as a result a number of amendments to the text were proposed. However, where the refinements in testing suggested in the documents appeared to complicate the process of identification unnecessarily, their adoption was not recommended.

6.9 Tests for non-specific impurities, heavy metals, lead, arsenic. It was noted that diverse comments had been received on the value of these tests but it was agreed that in general it would be inadvisable to adopt an elaborate scheme for testing for non-specific impurities such as chloride and sulfate. The Committee agreed that materials of exceedingly high purity are not necessary for medicinal purposes, provided that a reliable assay method and limit tests for likely impurities are available. This view confirmed the recommendation of the Expert Committee in its thirteenth report in respect to providing standards to insure adequate purity for medicinal purposes without unduly increasing the cost of treatment.

A working group examined a document proposing principles for limit tests for acidic and alkaline impurities,<sup>1</sup> which had been submitted before the session, and it was agreed that this system should be followed as far as possible in drafting the monographs for the second edition.

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<sup>1</sup> Unpublished working document WHO/Pharm/Ed.Sec./49

In the first edition of the I.Ph. separate limit tests were included for heavy metals and lead so that one or the other could be taken by the national authorities according to their preference. The Expert Committee reviewed the comments which had been received and, on the basis of these and their own experience, recommended that consideration should be given to retaining only a revised general test for heavy metals in the second edition, and retaining the specific test for lead in the few instances that such appeared desirable.

Two arsenic limit tests were included in the first edition, but the consensus appeared to be that method A (see Appendix 10, vol. I) is the better procedure and that only this method should be retained in the second edition.

The Expert Committee expressed the opinion that the inclusion of limits for heavy metals, lead, and arsenic in individual monographs should be reviewed critically as these impurities are now less common.

6.10 Assay procedures. It was agreed to adopt, where appropriate, certain new techniques such as non-aqueous titration of weak acids and weak bases, complexone methods for calcium and some other metals, ultra-violet spectrophotometry, and electrometric determination of end-points; proposals submitted by the members of the Expert Advisory Panel and others, would be examined later. The Expert Committee discussed the advisability of applying infra-red spectrophotometry. It was agreed that although such procedures require the use of expensive apparatus, infra-red data would be valuable as a means of identification. It was agreed to include infra-red methods in the second edition wherever desirable.

6.11 Melting, congealing and boiling ranges. Several reports on the determination of melting-range had been received and it was agreed that for the second edition the capillary tube method should be retained. However the method included in volume I of the first edition might be modified in certain minor respects. Consideration would also be given to including a determination with a heated block in suitable instances.

A number of comments had been received on the method included in the first edition for boiling range, notably on the fragility of the apparatus and the difficulty in obtaining it. In view of this, it was agreed to consider specifying apparatus similar to that described in the British Pharmacopoeia 1958, which appears to be readily available. A semi-micro method of determining boiling-points for identification purposes would also be studied.

6.12 Tests for sterility. It was agreed that the tests for sterility should be revised taking into account the various sterile preparations for which they would be required, including a number of antibiotics and other substances that present special problems. It was agreed to ask the Expert Advisory Panel on Biological Standardization to prepare a draft text which could be examined in collaboration with some members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. It was expected that in this way a test might be prepared in line with that to be recommended by WHO in "Recommended Requirements" issued for vaccines and other biological requirements.

6.13 Powders and sieves. Comments had been received from the International Standardization Organization on the appendix on powders and sieves included in the first edition and it was agreed to maintain collaboration with a view to revising the appendix if necessary.

6.14 Chemical names and graphic formulas. It was agreed to adopt a number of general principles<sup>1</sup> in agreement with the rules for organic chemical nomenclature issued by the International Union of Pure and Applied Chemistry. These principles and the Ring Index (Patterson & Capell) should form the basis of nomenclature and graphic formulas for the second edition.

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<sup>1</sup> WHO/Pharm/Ed.Sec./62

6.15 Incompatibilities. A number of requests for the inclusion of information on incompatibilities have been received. The Expert Committee agreed that the problem is too complex to be solved by the insertion of short statements in the I.Ph. However it was suggested that the publication of articles on incompatibilities of all kinds, physical, chemical and pharmacological, in the Bulletin of the World Health Organization should be encouraged.

6.16 Pharmaceutical radioactive isotopes. The Committee noted that a working group had been formed to supply specifications on pharmaceutical radioactive isotopes used in medicine.

6.17 Pharmacological indications and posology. The Expert Committee discussed a number of comments on the tables of doses of the first edition and considered the possibility of arranging the material in the most convenient manner in the light of experience gained with the first edition and of including additional information which might be of service to the users of the book. It was agreed to recommend that information on doses should be included in the individual monographs and that the same information should appear in tabular form in an appendix. The information should include the route of administration and any special indications that might be appropriate. Further, it was agreed that an indication of the pharmacological class of the preparation should be given in the monographs. It was also agreed that the implementation of the decision should be studied by a working group consisting of members of the Expert Advisory Panel and discussed by correspondence and at future sessions of the Expert Committee.

## 7. International Non-Proprietary Names

The Expert Committee reviewed the report of its Sub-Committee on Non-Proprietary Names.<sup>1</sup> It was noted that, thanks to the extensive correspondence that had been conducted between members of the Expert Advisory Panel before the meeting, it was possible to agree on many new proposed international non-proprietary names and that these names will be issued shortly in two separate lists. The general principles

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<sup>1</sup> WHO/Pharm/344

for guidance in devising international non-proprietary names had been examined in the light of comments received, and a few amendments had been made. The Committee welcomed the proposal to publish, as a separate document, a consolidated list of all the proposed and recommended international non-proprietary names which had so far been issued. The list would give the names in alphabetical order with their chemical name or description, including, if possible, the graphic formulas and a reference to the list in which they had first appeared, and would show whether the name had progressed from the status of a "proposed" to a "recommended" name.

The Committee expressed the view that consideration should be given to the inclusion of comments, where applicable, on the proposed names to which formal objections had been sustained.

The Committee noted that a report had been submitted at the Conference of the International Bureau for the Protection of Industrial Property held in Lisbon in October 1958 explaining why the Bureau had not been requested to include an article concerning non-proprietary names in the Paris Convention.<sup>1</sup>

#### 8. Information Sheets

The Secretary reported on the study and action undertaken to implement the programme on information sheets described in a report of a Study Group on the Use of Specifications for Pharmaceutical Preparations<sup>2</sup> and in the fifteenth report of the Expert Committee. Contact has been established with certain manufacturers or representatives of groups of manufacturers in different countries in order to examine with them what information they could supply direct on specifications for new important pharmaceutical preparations as set out in Annex 1 to the above-mentioned Expert Committee report. This would apply particularly in countries where there does not exist an active organization such as a Pharmacopoeia Commission which can supply the required information. Further efforts could be made in order to obtain the active co-operation from these different sources.

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<sup>1</sup> WHO/Pharm/349

<sup>2</sup> Wld Hlth Org. techn. Rep. Ser. 138

The programme is of great importance as it would make it possible to supply, without undue delay, the necessary information on new pharmaceutical preparations to authorities dealing with regulations on pharmaceutical preparations or initiating a laboratory control of them. The opinion was expressed that not only will the information sheets be of direct assistance to the national health administrations, but they will provide a means of soliciting comments and suggestions which would be useful as a basis of specifications to be included in the I.Ph.

9. Centre for Authentic Chemical Substances

A comprehensive report was made to the Committee on the activity of the WHO Centre for Authentic Chemical Substances. It was reported that there had been a substantial demand from all parts of the world during the past year for each of the eight authentic specimens now held for distribution. The original stock of one of the substances, d-tubocurarine, was nearly exhausted and replacement was under way. Another substance, beta-carotene, was also nearing exhaustion but there were no plans for renewing the stock since it is not needed especially in checking the quality of drugs but rather in testing foods. The Committee recommended that grateful thanks be expressed to the Apotekens Kontrollaboratorium which thus far has carried the full burden of administering this programme. It was reported that the WHO Centre for Authentic Chemical Substances had been carrying out an investigation into the possibility of providing a series of authentic chemical substances intended to serve as standards for the determination of melting-points as recommended by the Expert Committee in its fifteenth report. The Expert Committee agreed that the basis suggested by the Apotekens Kontrollaboratorium would be a satisfactory one and that specimens should be collected and collaborative tests carried out to establish the exact melting-point of these substances. The provision of a series of standards for calibrating spectrophotometers, which had also been suggested by the Expert Committee in its fifteenth report, was also under study and the report would be circulated at a later date. In this connexion the practice adopted for the next edition of the United States Pharmacopeia was reported to the Committee, whereby authentic specimens of about 60 additional drugs will be

made available for use in spectrometric tests and assays. The latter involve both ultra-violet and infra-red methods where it was found that certain errors may be avoided by employing the specimens. The possibility was suggested by the Committee that if it proved desirable to specify the use of such reference standards, they might be distributed as WHO Authentic Chemical Substances.

#### 10. Classification of Pharmaceutical Preparations

A resolution was received from the General Assembly of the International Pharmaceutical Federation, held at Brussels, 8-13 September 1958,<sup>1</sup> regarding principles in the classification of toxic and other substances used in therapeutics. Members of the Committee explained the steps taken in their countries to control the availability of various types of medicinal preparations in the interest of public health. It was agreed that this subject was of the greatest importance and that in addition to those substances usually considered to be "toxic" there were many preparations the use of which required supervision, and which should be made available to the patient only on the prescription of a medical practitioner. The Committee recommended that a careful study should be made of the problem and members agreed to send reports.

#### 11. Plastic Materials

The Expert Committee took note of the problems arising out of the increasing use of plastic materials, for packaging, containers and closures. It was agreed that a working group should be asked to report on the problem, and particularly on the use of plastic containers for solutions for injection, which are already in use in many countries.

#### 12. Poison Control Centres

The Committee received with interest reports from both Canada and the United States of America on the progress in organizing a nation-wide system of centres from which information on poisons and the treatment of poisoning may be

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<sup>1</sup> Annex 2

obtained at very short notice. This information is intended to facilitate rapid identification of agents, particularly household remedies and chemicals, suspected of having caused symptoms of poisoning and to assist physicians in deciding upon the most appropriate treatment. The Committee regarded these Centres as important contributions to a public health service and considered that the proposed information sheets might provide certain particulars helpful to the work of the Centres.

### 13. Unpublished Working Documents

- Baggesgaard Rasmussen, H. Chemical names and graphic formulas (WHO/Pharm/Ed.Sec./62)
- Diding, N. Centre for Authentic Chemical Substances -  
Report on the work in 1958 (WHO/Pharm/355)  
Centre for Authentic Chemical Substances -  
Addition of new substances (WHO/Pharm/356)
- Merz, H. W. Class of pharmaceutical preparation (WHO/Pharm/343 Add.1)
- Miller, L. C. Melting-temperature (WHO/Pharm/177)
- Secretariat International Pharmacopoeia Second Edition  
(WHO/Pharm/Ed.Sec./51)  
Style and arrangement of monographs (WHO/Pharm/Ed.Sec./53)  
General Notices (WHO/Pharm/Ed.Sec./54)  
Identification tests (WHO/Pharm/Ed.Sec./55)  
Purity tests (WHO/Pharm/Ed.Sec./56)  
Methods of Assay (WHO/Pharm/Ed.Sec./57)  
Class of pharmaceutical preparations (WHO/Pharm/Ed.Sec./59)  
International non-proprietary names (WHO/Pharm/349)
- Stevens, C. C. Information sheets (WHO/Pharm/347)
- van Os, D. Identification tests (WHO/Pharm/Ed.Sec./29 Rev.1)

SECOND EDITION OF THE I.P.H.

PROVISIONAL LIST OF ADDITIONS AND DELETIONS

ADDITIONS

Acetazolamide  
Acetazolamide Tablets  
Acetazolamide Sodium for Injection  
Amethopterin  
Amethopterin Tablets

Benzathine Penicillin  
Benzathine Penicillin Tablets  
Benoxinate Hydrochloride  
Benoxinate Hydrochloride Ophthalmic  
Solution

Betazole Hydrochloride  
Betazole Hydrochloride Injection  
Bethanechol Chloride  
Bethanechol Chloride Injection  
Bethanechol Chloride Tablets  
Busulfan  
Busulfan Tablets

Calcium Disodium Edetate  
Calcium Disodium Edetate Injection  
Carbromal  
Carbromal Tablets  
Carbutamide

Cetyl Pyridinium Chloride  
Cetyl Pyridinium Chloride Solution  
Chloramphenicol Palmitate  
Chloramphenicol Palmitate Oral  
Suspension

Chlormerodrin  
Chlormerodrin Tablets  
Chlormethin Hydrochloride  
Chlormethine Injection  
Chlorothiazide  
Chlorothiazide Tablets

Chlorpheniramine Maleate  
Chlorpheniramine Maleate Injection  
Chlorpheniramine Maleate Syrup  
Chlorpheniramine Maleate Tablets  
Chlorquinaldol  
Chlorquinaldol Ointment  
Cholesterol  
Cyclizine Hydrochloride  
Cyclizine Hydrochloride Tablets  
Cyclobarbital  
Cyclobarbital Tablets  
Cyclopentolate Hydrochloride  
Cyclopentolate Hydrochloride Ophthalmic  
Solution

Dehydrocholic Acid  
Dextran Injection  
Dextromoramide  
Diaphenylsulfone  
Diaphenylsulfone Tablets  
Diatrizoate Sodium  
Diatrizoate Sodium Injection  
Diethyl p-nitrophenyl Phosphate (dispensed  
as a 1.66% mixture with sodium chloride)  
Disodium Edetate  
Doxylamine Succinate  
Doxylamine Succinate Tablets

Edrophonium Chloride  
Edrophonium Chloride Injection  
Evans Blue  
Evans Blue Injection

Ferrous Gluconate

Annex 1

Glycobiarsol	Nitrofurantoin
Glycobiarsol Tablets	Nitrofurantoin Oral Suspension
	Nitrofurantoin Tablets
Helium	Novobiocin Calcium
Hydrocortisone Sodium Succinate for Injection	Novobiocin Calcium Oral Suspension
Hydroxyamphetamine Hydrobromide	Novobiocin Sodium
Hydroxyamphetamine Hydrobromide Ophthalmic Solution	Novobiocin Sodium Capsules
	Nystatin
Iodipamide Methylglucamine Injection	Nystatin for Oral Suspension
Isoflurophate	Nystatin Ointment
Isoflurophate Ophthalmic Solution	Nystatin Tablets
	Papaverine Sulfate
Leucoverin Calcium	Paramethadione
Leucoverin Calcium Injection	Paramethadione Capsules
Levallorphan Tartrate	Pentamidine Isothionate
Levallorphan Tartrate Injection	Pentamidine Injection
Lucanthone Hydrochloride	Peppermint leaves (to give a generally applicable method for the determination of volatile oil in vegetable drugs)
Lucanthone Tablets	Phenindamine Tartrate
	Phenindamine Tablets
Mecamylamine Hydrochloride	Phenoxymethylpenicillin
Mecamylamine Hydrochloride Tablets	Phenoxymethylpenicillin Calcium
Mechlorethamine Hydrochloride	Phenoxymethylpenicillin Potassium
Mechlorethamine Hydrochloride for Injection	Phenoxymethylpenicillin Tablets
Meclizine Hydrochloride	Phentolamine Methanesulfonate
Meclizine Hydrochloride Tablets	Phentolamine Methanesulfonate for Injection
Mephentermine Sulfate	Phytonadione
Mephentermine Sulfate Injection	Phytonadione Suspension, Sterile
Mephobarbital	Phytonadione Tablets
Mephobarbital Tablets	Piperazine Adipate
Meprobamate	Piperazine Adipate Tablets
Meprobamate Tablets	Piperazine Citrate
Mercaptopurine	Piperazine Phosphate
Mercaptopurine Tablets	Piperazine Phosphate Tablets
Methylene Blue	Piperocaine Hydrochloride
Methylene Blue Injection	Piperocaine Hydrochloride Injection
Methylergometrine Maleate	Piperocaine Hydrochloride Ophthalmic Ointment
Methylergometrine Injection	Polyethylene Glycol 400 (suitable for injecti

Annex 1

Polyoxyl 40 Stearate  
Polysorbate 80  
Polyvinylpyrrolidone  
Prednisolone  
Prednisolone Acetate  
Prednisolone Tablets  
Prednisone  
Prednisone Acetate  
Prednisone Tablets  
Probenecid  
Probenecid Tablets  
Prochlorperazine Dimaleate  
Prochlorperazine Dimaleate Injection  
Prochlorperazine Dimaleate Tablets  
Procyclidine Hydrochloride  
Procyclidine Tablets  
Propantheline Bromide  
Propantheline Bromide Injection  
Propantheline Bromide Tablets  
Propylene Glycol  
Propylhexedrine  
Propylhexedrine Inhalant  
Psyllium Seed (to give a generally applicable method for the determination of the swelling factor of vegetable drugs)  
Pyridostigmin Bromide  
Pyridostigmin Bromide Tablets  
  
Rhatany Root (to give a generally applicable method for the determination of tannins in vegetable drugs)  
  
Fauwolfia Root  
Reserpine  
  
Senega Root (to give a generally applicable method for the determination of saponins in vegetable drugs)  
Sodium Levothyroxine  
Sodium Levothyroxine Tablets  
Sodium Liothyronine  
Sodium Liothyronine Tablets  
  
Sulfacetamide Sodium  
Sulfacetamide Sodium Ophthalmic Ointment  
Sulfacetamide Sodium Ophthalmic Solution  
Sulfisoxazole  
Sulfisoxazole Tablets  
Sulfisoxazole, Acetyl  
Sulfisoxazole, Acetyl, Oral Suspension  
Sulfisoxazole Diethanclamine  
Sulfisoxazole Diethanolamine Injection  
Sulfisoxazole Diethanolamine Ophthalmic Ointment  
Sulfisoxazole Diethanolamine Ophthalmic Solution  
Sulfoxone Sodium  
Sulfoxone Sodium Tablets  
  
Testosterone Cyclopentylpropionate  
Testosterone Cyclopentylpropionate Injection  
Testosterone Enanthate  
Testosterone Enanthate Injection  
Thiamylal Sodium for Injection  
Tolbutamide  
Tolbutamide Tablets  
Trimethaphan Camphorsulfonate  
Trimethaphan Camphorsulfonate Injection  
  
Warfarin Sodium  
Warfarin Sodium Injection  
Warfarin Sodium Tablets  
  
Zoxazolamine  
  
DELETIONS  
  
Aconiti Tuber  
Barbitalum  
Butylis Aminobenzoas  
Cocaini Nitras  
Colchici Semen  
Compressi Barbitali  
Conessini Hydrobromidum  
Hydrargyri Iodidum Rubrum  
Scillae Bulbus  
Streptomycini et Calcii Chloridum  
Streptomycini Hydrochloridum  
Tinctura Aconiti  
Tinctura Belladonnae  
Tinctura Colchici  
Tinctura Scillae

I. Resolutions taken at the XVII General Assembly of the International Pharmaceutical Federation, Brussels, 8-13 September 1958

A. During recent years, the International Pharmaceutical Federation (I.P.F.) has followed with increasing interest the activities of the World Health Organization in the field of medicaments which are essential for the maintenance or re-establishment of the health of people the world over. In 1953, it appointed a liaison officer to establish closer contacts between WHO and I.P.F., in accordance with Article 3, paragraph 1, of its statutes. On the occasion of its XVIIth General Assembly in Brussels, in the light of the work already accomplished, and in particular:

- (1) the publication of Volumes I and II of the first edition of the International Pharmacopoeia and of a Supplement;
- (2) the preparation of other specifications for the examination of the quality of chemical products and drugs used in medicine;
- (3) the establishment of reference chemical substances;
- (4) the establishment of international biological standards and of international reference preparations;
- (5) the attribution of international non-proprietary names for pharmaceutical preparations, and considering the rapidly increasing numbers of new pharmaceutical products;

the International Pharmaceutical Federation decides to encourage WHO to intensify this work in the interests of public health, and to recommend all governments to support WHO in this important task.

B. Whereas there are, in the different countries, wide divergences in the regulations governing poisons intended for therapeutic use - divergences which tend to cause serious complications in the supply of medicaments to the public;

Annex 2

Whereas the World Health Organization is already engaged in preparing and establishing useful specifications, such as those of the International Pharmacopoeia, for the purpose of facilitating on the international plane the examination, analysis and the dispensing of medicaments;

1. The International Pharmaceutical Federation expresses the wish that the WHO will be able, as suggested by a study group of WHO set up to examine the use of specifications for pharmaceutical preparations, to undertake a study with the object of obtaining uniformity in the principles of classification of toxic substances used in therapeutics in the different countries.

In particular, it would be advantageous to study the possibility of establishing a list of toxic substances used in therapeutics in respect of which proposals on labelling and supply to the public might be made to the Governments of the different countries.

2. The International Pharmaceutical Federation offers to collaborate in these tasks and to make available its experience of questions concerning the supply of pharmaceutical preparations.

II. Resolution taken at the IV Pan-American Congress of Pharmacy and Biochemistry, Washington D.C., 3-9 November 1957

WHEREAS:

The valuable contributions of the World Health Organization in the field of pharmaceutical preparations toward promoting better public health and international commerce have been noted; and

Both Volumes I and II of the first edition of the International Pharmacopoeia have been published in Spanish and a Supplement to this edition is nearing completion,

The Fourth Pan-American Congress of Pharmacy and Biochemistry

RESOLVES:

That the World Health Organization be commended and encouraged to continue its work toward the establishment of proposed specifications and of appropriate tests for pharmaceutical preparations.