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No. 43

EXPERT COMMITTEE
ON THE
INTERNATIONAL PHARMACOPOEIA

Report on the Eighth Session

Geneva, 19-28 April 1951

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WORLD HEALTH ORGANIZATION
PALAIS DES NATIONS
GENEVA
NOVEMBER 1951

EXPERT COMMITTEE ON THE INTERNATIONAL PHARMACOPOEIA

Eighth Session

Members :

Dr. H. Baggesgaard Rasmussen, Professor of Organic Chemistry, Royal Danish School of Pharmacy, Copenhagen, Denmark; Member of the Danish Pharmacopoeia Commission

Dr. I. R. Fahmy Bey, Professor of Pharmacognosy, Faculty of Medicine, 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, formerly 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 de la Pharmacopée française

Dr. C. Heymans, Professor of Pharmacology and Toxicology, University of Ghent, Belgium

Dr. L. C. Miller, Director of Revision of the Pharmacopoeia of the United States of America, New York, N.Y., USA

Dr. D. van Os, Professor of Pharmacy and Toxicology, University of Groningen, Netherlands; Chairman, Netherlands Pharmacopoeia Commission (*Vice-Chairman*)

Observer :

C. Mentha, Director, United International Offices for the Protection of Industrial, Literary and Artistic Property, Berne, Switzerland

Secretary :

P. Blanc, Chief, Pharmaceutical Section, WHO

The report on the eighth session of this committee was originally issued in mimeographed form as document WHO/Pharm/150, 22 May 1951.

EXPERT COMMITTEE

ON THE

INTERNATIONAL PHARMACOPOEIA *

Report on the Eighth Session ¹

The Expert Committee on the International Pharmacopoeia held its eighth session in Geneva from 19 to 28 April 1951.

The Deputy Director-General opened the session and welcomed its members. He stressed the importance of establishing common standards of purity and potency for drugs in the different countries through the *Pharmacopoea Internationalis* (Ph.I.) and indicated that the Ph.I. would be of special interest to countries lacking financial resources for preparing a national pharmacopoeia. National commissions were at work in several countries to prepare a first or a new edition of their national pharmacopoeia. They had asked WHO to provide them with the necessary basis for their work and were counting on the Ph.I. All the Member States, after the publication of volume I of the Ph.I., would be invited to include all or part of its provisions in the national pharmacopoeias after the adoption of the said provisions by the authorities responsible for the pharmacopoeias. The Deputy Director-General indicated that the Expert Advisory Panel on the International Pharmacopoeia and WHO had been asked to study methods used in the control, advertising, and labelling of drugs and to prepare recommendations in this field for the protection of public health and to facilitate international commerce. That work also included the establishment of international non-proprietary names for important new drugs moving in international commerce and it would be the particular objective of the forthcoming second session of the Subcommittee on Non-Proprietary Names.²

* Formerly entitled "Expert Committee on the Unification of Pharmacopoeias".

¹ The Executive Board, at its eighth session, adopted the following resolution :

The Executive Board

1. NOTES the report of the Expert Committee on the International Pharmacopoeia on its eighth session ;
2. THANKS the members of the committee for their work ;
3. AUTHORIZES publication of the report, and
4. RECOMMENDS that the ninth session of the committee be held in 1951.
(Resolution EB8.R39, *Off. Rec. World Hlth Org.* 36, 12)

² See Annex 3, page 25.

The Director of the Division of Therapeutic Substances thanked the members of the committee, on behalf of WHO, for the large amount of work they had contributed, particularly Dr. Hampshire for all he had done on the preparation of the original text, and Professor Hazard for his special work on the French edition.

1. Resolutions Adopted at the Seventh Session of the Executive Board

The committee noted that the Executive Board had approved the recommendations made by the committee at its seventh session³ and by the Subcommittee on Non-Proprietary Names at its first session.⁴

2. Negotiations Regarding, and Establishment of, the Permanent International Pharmacopoeia Secretariat

The Chief of the Legal Office reported that, as a result of negotiations with the Belgian Government, WHO constituted the permanent International Pharmacopoeia Secretariat as from 1 January 1951. The Chairman expressed the appreciation of the committee to the Belgian Government for the laudable spirit of international co-operation which had made their agreement on the matter possible.

2.1 *Brussels Agreement, 1929, and the Pharmacopoea Internationalis*

The Chief of the Legal Office said that, although it now appeared that the provisions of the Ph.I. would adequately replace those of the 1929 Brussels Agreement, the Agreement was a diplomatic instrument which was binding on its signatories whereas the Ph.I. was in effect a recommendation and therefore not legally binding upon the Member States of WHO.

The committee made the following recommendation :

The Expert Committee on the International Pharmacopoeia

NOTES with satisfaction that WHO has become, since 1 January 1951, the permanent International Pharmacopoeia Secretariat in application of Article 35 of the Agreement revising the Agreement respecting the Unification of Pharmacopoeial Formulas for Potent Drugs, signed at Brussels on 20 August 1929 ;

Considering that this status reinforces the authority of WHO to stress to the States concerned that some of the technical provisions of the above Agreement are obsolete, in particular following the adoption in the *Pharmacopoea Internationalis* of standards and principles in accordance with the latest developments of science, and

³ Resolution EB7.R79, *Off. Rec. World Hlth Org.* 32, 33

⁴ Resolution EB7.R73, *Off. Rec. World Hlth Org.* 32, 30

Considering that it is undesirable to maintain contradictory provisions,

1. RECOMMENDS that the Director-General invite the Member States of WHO, and those States which are not members but are parties to the said 1929 Brussels Agreement, to take note of the fact that some of the technical provisions of the said Agreement are obsolete and that it is desirable to replace them by the provisions of the *Pharmacopoea Internationalis* ;
2. SUGGESTS that an annex showing the specifications in the 1929 Brussels Agreement which differ from the specifications in the *Pharmacopoea Internationalis*, first edition, volume I, be included with the circular letter to be sent out for this purpose to the above-mentioned States ;
3. INVITES the Director-General to take steps to prepare regulations, to be adopted in accordance with Article 21 (*d*) of the WHO Constitution, in which the *Pharmacopoea Internationalis* would be embodied and which would replace the 1929 Brussels Agreement.

The Chairman submitted a list of changes made in monographs of volume I of the Ph.I. compared with the 1929 Brussels Agreement ; it was decided that, after revision, the list should be sent to all Member States and to all signatories of the 1929 Brussels Agreement with a circular letter.

The Chief of the Legal Office explained the procedure for giving effect to this recommendation and said that he believed that it would be possible to complete the necessary work in time to submit the final draft regulations to the World Health Assembly at its session in 1952.

3. International Non-Proprietary Names for Drugs

3.1 *Report of the Subcommittee on Non-Proprietary Names*

The committee noted that the report on the first session of the Subcommittee on Non-Proprietary Names had been approved by the Executive Board,⁵ and that the list of non-proprietary names adopted at that session was being forwarded to Member States, and to national pharmacopoeial commissions, with a circular letter from the Director-General. Since the last session lists had been submitted by national pharmacopoeial authorities, particularly in France and in the Scandinavian countries. They would be considered at the second session of the Subcommittee on Non-Proprietary Names when, on the basis of the experience acquired, modifications might be made to the plan originally adopted for creating and deciding on non-proprietary names. Correspondence had been exchanged with the World

⁵ Resolution EB7.R73, *Off. Rec. World Hlth Org.* 32, 30

Medical Association and with the Council on Pharmacy and Chemistry of the American Medical Association, as well as with the US delegation to the World Health Assembly, with particular reference to the consideration to be given to names suggested by discoverers of products.

The committee made the following recommendation :

The Expert Committee on the International Pharmacopoeia,

Considering the resolution WHA3.11,⁶ and

Recognizing that requests have been made by various authorities that, in choosing international non-proprietary names, the suggestions of the discoverer of the product in question shall be taken into consideration,

DESIRES to point out that the purpose of these requests is in harmony with the principles already adopted,⁷ and that any name suggested by the discoverer which does not conflict with these principles will be considered sympathetically.

The following further recommendation was made :

The Expert Committee on the International Pharmacopoeia

RECOMMENDS that the Subcommittee on Non-Proprietary Names which was originally to consist of three members⁸ should consist of four members.

3.2 *Relations with the International Union for the Protection of Industrial Property*

The Director of the International Union for the Protection of Industrial Property⁹ stated that his organization could provide information on internationally registered trademarks, and possibly on nationally registered trademarks, by search in the registers of each signatory country to the Union Convention of Paris, 20 March 1883, for the Protection of Industrial Property, revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at The Hague on 6 November 1925, and in London on 2 June 1934.

The Chief of the Legal Office indicated that provisions existed in the Union Convention of Paris, 1883, under which the names and emblems of one State used as trademarks might be rejected, prohibited, or invalidated in other member countries of the Union. Modern international law recognized international organizations as having legal capacity. It

⁶ *Off. Rec. World Hlth Org.* 28, 19

⁷ *Off. Rec. World Hlth Org.* 25, 8; see also Annex 3, Appendix 1, page 29.

⁸ Resolution EB6.R29, *Off. Rec. World Hlth Org.* 29, 12

⁹ The full title of this union is : United International Offices for the Protection of Industrial, Literary and Artistic Property.

might therefore be possible, at the next meeting of the Union, to be held in Lisbon probably in 1953, to insert an additional provision in the Convention, securing special protection for international non-proprietary names adopted by WHO.

The Director of the Union confirmed the views so expressed.

The following resolution was adopted by the committee :

The Expert Committee on the International Pharmacopoeia,

Considering that by resolution EB7.R79¹⁰ the Executive Board, on the basis of the report on the seventh session of the Expert Committee on the Unification of Pharmacopoeias,¹¹ requested the Director-General to continue studying the problem of the protection of non-proprietary names and to explore the possibilities offered by the International Union for the Protection of Industrial Property, Berne ;

Considering that the possibilities offered should be taken into account and that the necessary steps to this effect should be taken in collaboration with the International Union ;

Considering that following this recommendation the Director-General invited the Director of the International Union for the Protection of Industrial Property, Berne, to participate in the work of the committee ;

Considering that the representative of the International Union has effectively participated in this work and provided useful information concerning the possibility of amending the International Convention, which created the International Union for the Protection of Industrial Property, signed at Paris on 20 March 1883, and revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at The Hague on 6 November 1925, and in London on 2 June 1934, by inserting therein a provision for refusing or invalidating the registration of international non-proprietary names adopted by the expert committee and also for prohibiting their use in the countries which are members of the Union ;

1. EXPRESSES its gratitude to the Director of the International Union for co-operation given and promised ;
2. RECOMMENDS that the Director-General take, in co-operation with the International Union, the measures necessary with a view to the eventual inclusion in the Convention, which created the International Union for the Protection of Industrial Property, signed at Paris on 20 March 1883, and revised at Brussels on 14 December 1900, at Washington

¹⁰ *Off. Rec. World Hlth Org.* 32, 33

¹¹ *World Hlth Org. techn. Rep. Ser.* 1951, 35

on 2 June 1911, at The Hague on 6 November 1925, and in London on 2 June 1934, of suitable provisions for ensuring that international non-proprietary names have, in the general interest, the protection desired in the territory of the countries parties to the said Convention ; and

3. RECOMMENDS that the Director-General make the necessary arrangements with the International Union for the Protection of Industrial Property to facilitate the search for names which may previously have been registered.

3.3 *Protection of international non-proprietary names by Member States*

The following recommendation was made by the committee :

The Expert Committee on the International Pharmacopoeia,

Considering that by resolution WHA3.11¹² the Third World Health Assembly :

1. adopted the general principles enumerated by the Expert Committee on the Unification of Pharmacopoeias at its fifth session ; and

2. decided that the said committee would choose and approve international non-proprietary names for drugs which might be inserted in later editions of the *Pharmacopoea Internationalis* and that the Director-General of WHO should communicate these international non-proprietary names to Member States and to national pharmacopoeial authorities, recommending that the said names be officially recognized and adopted as international non-proprietary names ;

Considering that the same resolution stated that the recommendations of the Director-General should also include a request that such measures as may be deemed appropriate by Member States be taken with a view to preventing the use of names selected for unauthorized purposes, and in particular to prevent the granting of exclusive proprietary rights in these names to the manufacturer ;

Considering that international non-proprietary names are already being sent to Member States, and that the first volume of the *Pharmacopoea Internationalis* is being published ;

INVITES the Director-General

1. to keep himself informed of the way in which the recommendations given in the said resolution have been carried out when the first publication is made ;

¹² *Off. Rec. World Hlth Org.* 28, 19

2. to study whether such measures taken by Member States have led to an efficient protection of the international non-proprietary names chosen ; and
3. to prepare and submit to the World Health Assembly regulations based on Article 21 (d) and (e) of the Constitution to ensure legal protection of the international non-proprietary names.

4. Publication of the Pharmacopoea Internationalis, First Edition, Volume I

The Director of the Division of Editorial and Reference Services explained that arrangements had been made for an initial printing of 3,000 copies of the English edition, 2,500 copies of the French edition, and 2,500 copies of the Spanish edition. Each Member State would receive a copy accompanied by a circular letter from the Director-General. Copies would be sent to national public-health authorities, members of the Executive Board, members of the expert advisory panel, national pharmacopoeia commissions, and medical and pharmaceutical journals for review.

The committee recommended that no general permission should be given for publication or translation but that any Member State might be permitted to publish the Ph.I. in translation, for use as their national pharmacopoeia, or to incorporate part or the whole of the Ph.I. in their national pharmacopoeia, in which case WHO would assume no responsibility for the translation. If any country, or private or public body, wished to publish the work as a translation of the Ph.I., the responsibility would rest with WHO which would decide whether authorization should be granted and would control the translation.

The committee made the following recommendation :

The Expert Committee on the International Pharmacopoeia,

Considering that the *Pharmacopoea Internationalis*, first edition, volume I, is about to be published, and

Considering that it might be appropriate to grant financial support to certain countries planning translation of this volume,

RECOMMENDS the Director-General to examine individual requests from Member States with a view to obtaining from the Technical Assistance Board financial support for these Member States for translation of volume I into their national languages.

5. List of Synonyms of Drugs Included in the Pharmacopoea Internationalis, First Edition, Volume I

A working party, consisting of Professors Baggesgaard Rasmussen, Fahmy, Flück, and van Os and Dr. Miller, established principles for the guidance of the members of the committee in revising the list prepared

by WHO. It was agreed that a new draft should be submitted to the members with a view to its publication, as a supplement to the *Bulletin of the World Health Organization*, as soon as possible after the appearance of the Ph.I. The committee agreed that a draft list should be prepared of synonyms for drugs to be included in the *Pharmacopoea Internationalis*, first edition, volume II, following the same principles as for the list of synonyms for drugs in volume I.

6. Relations with Other WHO Expert Committees

6.1 *Expert Committee on Biological Standardization*

The committee noted with satisfaction that a number of draft monographs for drugs, and appendices referring to biological assays, for volume II, which had been submitted to the Expert Committee on Biological Standardization (Benzylpenicillinum, Penicillinatum, Dihydrostreptomycinum, Dimercaprolum (including toxicity test), Oxophenarsini Hydrochloridum, Streptomycinum, Tubocurarinum Chloridum, Pyrogen Test and Tests for Sterility) had been examined at the fourth session of that committee which had agreed to send final texts of the biological tests.

6.2 *Expert Committee on Malaria*

The committee noted the approval by the Expert Committee on Malaria of the antimalarial drugs to be included in the Ph.I., and agreed that a draft monograph be prepared on Primaquini Diphosphas.

6.3 *Expert Committee on Venereal Infections and Treponematoses*

The committee agreed to prepare a draft monograph on Podophylli Resina as suggested by the Expert Committee on Venereal Infections and Treponematoses.

6.4 *Subcommittee on Serology and Laboratory Aspects*

Reports had been received from Professor van Os and Dr. J. Ørskov on the physico-chemical tests of Cardiolipinum and Lecithinum. Other investigations were being made by two members of the committee, and Professor van Os undertook to present a draft monograph, based on their reports, after consultation with the New York State Department of Health. The Expert Committee on Biological Standardization had agreed to supply the information referring to the biological tests.

6.5 *Other expert committees*

The committee noted the comments received from the expert committees on leprosy, plague, and trachoma, and agreed to prepare a draft monograph on Terramycinum.

7. Relations with Other Organizations

7.1 *International Union of Chemistry*

Relations had been continued with the International Union of Chemistry to whom the task of preparing standards of purity for reagents in volume I of the Ph.I. had been entrusted, through their Commission for Standardization of the Purity of Chemical Products. Professor van Os reported that the Commission was prepared to establish and forward these standards to WHO as soon as possible, and he agreed to maintain contact with the Union Commission and to report to the committee at the next session.

The committee noted that, although there was no ruling by the International Union of Chemistry, the secretary of the Union had reported that there was growing support for the new nomenclature for quaternary ammonium salts, and it was agreed that those names, *Morphinii Chloridum* for example, should appear in the list of synonyms and should be incorporated in future editions of the Ph.I.

The committee expressed its thanks to the secretary of the International Union of Chemistry for checking the graphic formulae for the drugs.

7.2 *World Medical Association*

The committee noted that relations had been maintained with the World Medical Association, particularly regarding the Table of Usual and Maximal Doses for Adults for drugs to be included in the *Pharmacopoea Internationalis*, first edition, volume II, and that comments on that table were being received through the World Medical Association from different national medical associations. Correspondence had also been exchanged on non-proprietary names, and the committee expressed its thanks to the World Medical Association for their collaboration. The draft Table of Usual Doses of Drugs for Children would be submitted to the World Medical Association, as well as to the Expert Committee on Maternal and Child Health.

7.3 *International Pharmaceutical Federation*

It was reported that relations had been maintained with the International Pharmaceutical Federation, and that information had been sent to that body concerning the work on international non-proprietary names and the control of drugs.

8. Preparation of the *Pharmacopoea Internationalis*, First Edition, Volume II

Much of the session was concerned with completing draft monographs and appendices for volume II of the Ph.I. The committee noted that, since its seventh session, the Chairman had completed by

correspondence with the members the following monographs for printing in first proofs :

Acidum Undecylenicum	Injectio Nicotinamidi
Amodiaquini Hydrochloridum	Injectio Papaverini Hydrochloridi
Aqua Destillata	Injectio Pentetrazoli
Aqua pro Injectione	Injectio Pethidini Hydrochloridi
Bismuthi et Kalii Tartras	Injectio Picrotoxini
Compressi Acidi Acetylsalicylici	Injectio Progesteroni
Compressi Amidopyrini	Injectio Stibii et Kalii Tartratis
Compressi Aminophyllini	Injectio Stibii et Natrii Tartratis
Compressi Amphetamini Sulfatis	Injectio Stibii et Natrii Thioglycollatis
Compressi Carbarsoni	Injectio Stibopheni
Compressi Chiniofoni	Injectio Sulfadiazini Natrici
Compressi Dicoumaroli	Injectio Sulfamerazini Natrici
Compressi Digitalis	Injectio Sulfathiazoli Natrici
Compressi Ferrosi Sulfatis	Natrii Chloridum
Dichlorophenarsini Hydrochloridum	Procaini Benzylpenicillinum
Dihydrostreptomycinum	Propylthiouracilum
Gonadotrophinum Chorionicum	Streptomycini et Calcii Chloridum
Gonadotrophinum Sericum	Streptomycini Hydrochloridum
Injectio Aminophyllini	Streptomycini Sulfas
Injectio Bismuthi Subsalicylatis	Tinctura Aconiti
Injectio Coffeini et Natrii Benzoatis	Tinctura Belladonnae
Injectio Dextrosi	Tinctura Colchici
Injectio Emetini Hydrochloridi	Tinctura Hyoscyami
Injectio Ergometrini Maleatis	Tinctura Ipecacuanhae
Injectio Mersalyli et Theophyllini	Tinctura Scillae
Injectio Morphini	Tinctura Stramonii
Injectio Neostigmini Methylsulfatis	Tinctura Strychni
Injectio Nicethamidi	Tubocurarini Chloridum

as well as the general monographs on Injections and Tincturae, and the following appendices :

Biological Assay of Dihydrostreptomycinum
 Biological Assay of Gonadotrophinum Chorionicum
 Biological Assay of Gonadotrophinum Sericum
 Biological Assay of Streptomycinum
 Biological Assay of Tubocurarini Chloridum
 Determination of Methoxyl
 Test for Sterility of Streptomycinum

The committee considered many draft monographs¹³ together with comments on them and reports submitted by the members of the committee, and also noted certain helpful reports and comments submitted by other members of the expert advisory panel. In all, 202 draft monographs and 17 appendices have been submitted, of which 70 monographs and appendices have now been completed and released for printing, 36 monographs being

¹³ See Annex 2, page 21.

deferred for further study. The latter will involve consultation with specialists and especially actual laboratory tests of the proposed procedure to ensure a maximum degree of practicability. The committee agreed that, in view of the limited use of Metoponi Hydrochloridum, the further advice of the Expert Committee on Drugs Liable to Produce Addiction should be sought on the question of including this substance in the Ph.I.

8.1 *Basic drugs*

The following draft monographs were approved with amendments :

Acidum Para-Aminosalicilicum
Cholini Chloridum
Digitoxosidum
Hydrocodoni Bitartras
Hydromorphoni Hydrochloridum
Methadoni Hydrochloridum
Natrii Para-Aminosalicylas
Oxophenarsini Hydrochloridum
Oxycodoni Hydrochloridum
Suraminum Natriicum
Thyroides

Improved tests for rapid identification of the new morphine substitute, Methadoni Hydrochloridum, were adopted. A proposed toxicity test for Oxophenarsini Hydrochloridum was considered and held over for further advice from the Expert Committee on Biological Standardization. The committee adopted proposed specifications for Acidum Para-aminosalicilicum and Digitoxosidum, which described products of high purity. These specifications make it possible, in the case of Digitoxosidum, to avoid the biological assay.

An important decision was reached with respect to Thyroides whereby the latter would be standardized according to its content of thyroxine iodine. A significant regional difference was noted in regard to Glycerolum ; it was decided to provide monographs for both substantially pure glycerol and that which contains some 13% of water.

8.2 *Compressi*

Since many of the drugs of the Ph.I. are dispensed in the form of coated tablets, the assay of this pharmaceutical form was discussed on the basis of a report submitted by one of the members. It was decided to include this subject in the general monograph on Compressi, along with a requirement that colours and other ingredients of the coating should be innocuous ; the Latin title, Compressi Obducti, was adopted for coated tablets.

The following monographs were adopted with amendments :

Compressi	Compressi Natrii Salicylatis
Compressi Aethisteroni	Compressi Neostigmini Bromidi
Compressi Atropini Sulfatis	Compressi Pethidini Hydrochloridi
Compressi Calcii Gluconatis	Compressi Phenacetini
Compressi Chloroquini Diphosphatis	Compressi Santonini
Compressi Hydrargyri Subchloridi	Compressi Succinylsulfathiazoli
Compressi Hydromorphoni Hydrochloridi	Compressi Sulfaguanidini
Compressi Hyoscini Hydrobromidi	Compressi Sulfamerazini
Compressi Menadioni	Compressi Sulfanilamidi
Compressi Mepacrini Hydrochloridi	Compressi Sulfathiazoli
Compressi Methyltestosteroni	Compressi Theobromini Natrici et Natrii Acetatis

The committee decided that the monograph on Compressi Morphini Sulfatis should describe tablets suitable for hypodermic injection. They agreed not to publish this monograph until general agreement had been reached to include hypodermic tablets in the Ph.I.

8.3 *Injectiones*

The committee noted that the only assay procedures available for certain injections required rather large quantities; this was considered sufficient grounds for omitting the assay in such cases. Nevertheless, it was decided that some benefit would be derived from having an official description for these injections, which include :

Injectio Apomorphini Hydrochloridi	Injectio Lobelini Hydrochloridi
Injectio Atropini Sulfatis	Injectio Physostigmini Salicylatis
Injectio Coffeini et Natrii Salicylatis	Injectio Physostigmini Sulfatis
Injectio Desoxycortoni Acetatis	Injectio Riboflavini
Injectio Hyoscini Hydrobromidi	Injectio Strychnini Nitratis

The drafts of the following monographs complete with assays were approved, as revised, and released for printing : Injectio Calcii Gluconatis, Injectio Dihydrostreptomycini, Injectio Heparini, and Injectio Procaini Hydrochloridi.

It was agreed that a draft monograph on Injectio Adrenalini Bitartras should be prepared.

Because some drugs which must be given by injection are unstable in the form of solutions, the Ph.I. makes provision for such drugs to be supplied as sterile powders in sealed containers. Since these powders naturally differ from injections which are already in the form of solutions, the committee was faced with certain problems to which it will give further study.

The committee agreed to insert, in appropriate cases, a requirement that the lot number of the manufacturer and the expiration date should

be stated on the label, and that a statement of the strength to be supplied, when the injection was ordered with no strength being stated, might also be included in the appropriate monographs.

8.4 *Reference standards*

A problem carried over from the previous session concerned the necessity for establishing reference standards consisting of pure chemicals for several Ph.I. assays. A working party, consisting of Dr. Miller, Professor van Os, and Professor Fahmy, reported on this question, and the committee decided to describe these required standards as reagents in so far as possible.

8.5 *Sample size*

While the size of the sample examined greatly influences the confidence that may be placed in the assay result, it was agreed that practical and economic considerations limit the quantity that may be demanded. The committee decided to describe, wherever possible, assay methods having sufficient sensitivity for them to be applied to reasonably small samples. Where such assays are unavailable, the committee will undertake to devise more sensitive procedures, taking advantage if necessary of modern technical developments such as chromatographic adsorption, polarography, and spectrophotometry.

8.6 *Surgical suture materials*

The attention of the committee was drawn to the urgent need for international standards and tests for surgical suture materials. Steps to achieve uniformity in sterility testing were considered of particular importance. Three members undertook the task of proposing specifications based on a review of all existing standards, including those for size and tensile strength.

8.7 *Graphs for isotonic solutions*

The committee agreed upon the desirability of providing general directions for preparing isotonic solutions of many drugs in the Ph.I. A series of graphs to facilitate this had been submitted by one of the members. The committee decided to include such graphs as an appendix to volume II after they had been studied by the members.

8.8 *Procurement of samples of drugs for analytical purposes*

The committee noted that arrangements were being made by WHO to enable members to obtain, free of charge and without delay, samples for any analytical and other investigations they might undertake for the preparation of the Ph.I.

8.9 *Table of Usual and Maximal Doses for Adults for drugs to be included in volume II*

The committee noted that the revised table prepared by Professor Hazard was now being circulated to national medical associations through the World Medical Association. The comments received would be considered for incorporation in a new draft of the table.

8.10 *Table of Usual Doses of Drugs for Children*

Professor Hazard reported that he had worked in collaboration with Professor Turpin who had given him much valuable assistance. He felt that the preface to the new table should indicate clearly that the table included only those drugs which were in the Ph.I. It should also be made quite clear that the table referred only to usual doses covering a period of 24 hours and in no way referred to maximal doses. He stressed that an age limit of 30 months had been laid down since that age was important physiologically. A considerable number of comments had been received from paediatricians in various countries and they were being incorporated as far as possible in the table. Weight and age had both been used in his table depending upon the drug in question.

In order to elicit further useful comments a report of the work might be subsequently published by Professor Hazard in the *Bulletin of the World Health Organization*. The committee agreed and thanked Professor Hazard for his work.

9. Fellowships

The Chief of the Fellowships Section announced that during 1950 a number of Fellows had worked on the control of drugs, on pharmacology, and on related subjects. Requests had already been received in 1951, as a result of the work accomplished, and a number of fellowships had been awarded. The fellowships were not restricted to the less developed countries; institutions in any country might apply through their national health-administration to the regional office. Health administrations were being asked to inform all the institutions concerned.

The committee agreed that Fellows should be selected with a view to their studying one of the following subjects:

(1) methods used in the preparation of pharmacopoeias, in laboratories—generally university laboratories—with professors or workers or members of national pharmacopoeial commissions engaged in research and the assaying of drugs in order to prepare the standards of drugs to be included in national pharmacopoeias or formularies or in the Ph.I.;

(2) methods for the control of drugs : this should be done either :

(a) at laboratories where drugs and specialities for the home market are officially tested for standards of purity and potency, packing, labelling, etc., in accordance with national and international requirements ; in different countries such control may be carried out : in state laboratories, in certain university laboratories, in laboratories of national authorized pharmaceutical associations, or in other laboratories ; or

(b) in the offices of officials responsible for preparing and enforcing the regulations on the control of drugs in different countries, with a view to preparing and unifying methods and regulations for a control of drugs in the various countries and to stimulating co-operation between health administrations responsible for the control of drugs ;

(3) the mechanism of action of drugs.

10. Preparation for a Conference on Drug Standards and on the Control of Pharmaceuticals

The committee noted the resolution adopted by the Executive Board ¹⁴ referring to a conference of representatives of administrations responsible for the control of drugs in the various countries to be convened to consider the advantage of uniform methods for the control of pharmaceuticals in the interests of health and international commerce. It was reported that, following recommendations made at the sixth session of the committee,¹⁵ a circular letter with a questionnaire had been sent out on 5 September 1950 to the Member States. Forty-one Member States had now answered the questionnaire in full, indicating a great interest. While it was not expected that WHO would undertake to issue regulations pertaining to this subject, the committee agreed that such a conference of representatives of national health-administrations dealing with the control of drugs in their respective countries, and of other specialists in that field, could serve to recommend general principles and indicate the methods to be used. These would be of particular service to less developed countries and other countries desiring to organize or to improve the control of pharmaceuticals within their territories. The committee noted in the course of the discussion that the World Medical Association and the International Pharmaceutical Federation had also considered these problems, and agreed that collaboration with these two organizations would be useful.

The work of preparation for such a conference could be done by correspondence and there would be only one session of the conference.

¹⁴ Resolution EB7.R79, *Off. Rec. World Hlth Org.* 32, 33

¹⁵ *World Hlth Org. techn. Rep. Ser.* 1950, 29, 15

Reports would be asked for from members of the expert advisory panel dealing with the control of pharmaceuticals and from other specialists in collaboration with national health-administrations. The reports would be circulated to the members of the panel. The committee agreed that the preparation for the conference could be made in order that it be convened in the autumn of 1953.

Annex 1

**PREPARATION OF DRAFT MONOGRAPHS, REPORTS,
AND EXPERIMENTAL INVESTIGATIONS**

Professor Baggesgaard Rasmussen agreed :

- To revise jointly with Professor van Os the test for *m*-aminophenol in Acidum Para-aminosalicylicum and Natrii Para-aminosalicylas
- To report jointly with Professor Fahmy on the test for *p*-aminobenzoic acid in Injectio Procaini Hydrochloridi
- To report jointly with Professor Flück on the melting-range of Digitoxosidum
- To report jointly with Professor Hazard on the quality of glass for injections
- To report jointly with Professors Flück and van Os on new methods of analysis
- To present a preface to the graphs for isotonic solutions

Professor Fahmy agreed :

- To re-draft the monograph on Chlorobutanolum
- To report jointly with Professor Baggesgaard Rasmussen on the test for *p*-aminobenzoic acid in Injectio Procaini Hydrochloridi
- To prepare jointly with Professor Flück a monograph on Podophylli Resina
- To prepare jointly with Dr. Miller a report on the chemical assay of Dihydrostreptomycinum
- To prepare jointly with Professor Flück a report on Cardiolipinum and Lecithinum

Professor Flück agreed :

- To prepare jointly with Professor Fahmy a monograph on Podophylli Resina
- To report jointly with Professor Baggesgaard Rasmussen on the melting-range of Digitoxosidum
- To report on the colour and clarity of a solution
- To check samples of Cardiolipinum and Lecithinum and prepare a report jointly with Professor Fahmy
- To report jointly with Professors Baggesgaard Rasmussen and van Os on new methods of analysis
- To report on reactions for water prepared by the ion-exchange method
- To prepare a draft monograph on Antazolini Chloridum

Dr. Hampshire agreed :

- To finalize for printing the monographs completed by correspondence
- To prepare draft monographs on : Adrenalini Bitartras
Injectio Adrenalini Bitartratis
Insulin
Protamine-Zinc Insulin
- To complete, by correspondence, those injection and tablet monographs not considered in detail by the committee during the eighth session
- To report on Injectio Procaini Benzylpenicillini Aquosa

Professor Hazard agreed :

- To revise the Table of Usual and Maximal Doses for Adults for the drugs to be included in the *Pharmacopoea Internationalis*, first edition, volume II, after receiving comments from the World Medical Association and others
- To report jointly with Professor Baggesgaard Rasmussen on the quality of glass for injections
- To continue his work on the Table of Usual Doses of Drugs for Children and to draft the preface to this table
- To report jointly with Dr. Miller and Professor van Os on suture materials

Professor Heymans agreed to prepare a draft monograph on Primaquini Diphosphas

Dr. Miller agreed :

- To report on the assay of Compressi Methyltestosteroni
- To report on the assay of Isoprenalinum and Arterenolum
- To re-draft the monograph on Injectio Bismuthi et Kalii Tartratis
- To prepare jointly with Professor Fahmy a report on the chemical assay of Dihydrostreptomycinum
- To report jointly with Professors Hazard and van Os on suture materials
- To report on the toxicity test for Oxophenarsini Hydrochloridum
- To prepare a draft monograph on Terramycinum

Professor van Os agreed :

- To report on the use of Reinecke's salt for the identification of Cholini Chloridum
 - To revise jointly with Professor Baggesgaard Rasmussen the test for *m*-aminophenol in Acidum Para-aminosalicylicum and Natrii Para-aminosalicylas
 - To report jointly with Professors Baggesgaard Rasmussen and Flück on new methods of analysis
 - To re-draft the monograph on Glycerolum
 - To re-draft the text on sugar-coated tablets
 - To report jointly with Professor Hazard and Dr. Miller on suture materials
 - To prepare the list of reagents for volume II of the Ph.I.
 - To prepare a draft monograph on Cardiolipinum et Lecithinum
 - To keep in touch with the International Union of Chemistry
-

Annex 2

**LIST OF MONOGRAPHS AND APPENDICES SUBMITTED FOR
INCLUSION IN THE PHARMACOPOEA INTERNATIONALIS,
FIRST EDITION, VOLUME II**

Monographs

Acetylcholini Chloridum	** Compressi Chloroquini Diphosphatis
Acidum Folicum	Compressi Codeini Phosphatis
** Acidum Para-aminosalicylicum	Compressi Colchicini
* Acidum Undecylenicum	* Compressi Dicoumaroli
Aethylis Chaulmoogras et Hydnocar- pas	Compressi Diethylstilboestrolis
* Amodiaquini Hydrochloridum	* Compressi Digitalis
* Aqua Destillata	Compressi Digitoxosidi
* Aqua pro Injectione	Compressi Ephedrini Hydrochloridi
Arterenoli Bitartras	Compressi Ergometrini Maleatis
Aureomycini Hydrochloridum	Compressi Ergotamini Tartratis
* Bismuthi et Kalii Tartras	* Compressi Ferrosi Sulfatis
Bismuthi Subnitras	Compressi Glyceryli Trinitratis
Calcii D-Saccharas	** Compressi Hydrargyri Subchloridi
Cardiolipinum et Lecithinum	** Compressi Hydromorphoni Hydrochlo- ridi
Chloramphenicolum	** Compressi Hyoscini Hydrobromidi
Chlorobutanolum	Compressi Lanatosidi C
Chlorocresolum	** Compressi Menadioni
Chlorophenothanum Technicum	** Compressi Mepacrini Hydrochloridi
** Choliiii Chloridum	** Compressi Methyltestosteroni
* Compressi Acidi Acetylsalicylici	** Compressi Morphini Sulfatis
Compressi Acidi Ascorbici	** Compressi Natrii Nitris
** Compressi Aethisteroni	** Compressi Natrii Salicylatis
* Compressi Amidopyrini	** Compressi Neostigmini Bromidi
* Compressi Aminophyllini	Compressi Nicotinamidi
* Compressi Amphetamini Sulfatis	Compressi Oestradioli
** Compressi Apomorphini Hydrochlo- ridi	** Compressi Pethidini Hydrochloridi
** Compressi Atropini Sulfatis	** Compressi Phenacetini
Compressi Barbitali	Compressi Phenobarbitali
Compressi Barbitali Natrici	Compressi Phenobarbitali Natrici
** Compressi Calcii Gluconatis	Compressi Proguanili Hydrochloridi
Compressi Calcii Lactatis	Compressi Quinidini Sulfatis
Compressi Carbacholi	** Compressi Quinini Sulfatis
* Compressi Carbarsoni	Compressi Riboflavini
* Compressi Chiniofoni	** Compressi Santonini
	** Compressi Succinylsulfathiazoli

* Completed and ready for printing.

** Discussed at the eighth session.

- Compressi Sulfadiazini
 ** Compressi Sulfaguanidini
 ** Compressi Sulfamerazini
 ** Compressi Sulfanilamidi
 ** Compressi Sulfathiazoli
 ** Compressi Theobromini Natrici et Natrii Acetatis
 Compressi Thiamini Hydrochloridi
 Conessini Hydrobromidum
 Cyanocobalaminum
 Dextranum Hydrolysatum
 Dextrosum
 * Dichlorophenarsini Hydrochloridum
 ** Digitoxosidum
 * Dihydrostreptomycinum
 Dimercaprolum
 Diphenhydramini Hydrochloridum
 Ethanolum
 Ethanolum Absolutum
 Ethanolum Dilutum
 Ethylenediamini Hydras
 Gallamini Triethiodidum
 ** Glycerolum
 * Gonadotrophinum Chorionicum
 * Gonadotrophinum Sericum
 Hexobarbitalum
 Hexobarbitalum Natricum
 ** Hydrocodoni Bitartras
 ** Hydromorphoni Hydrochloridum
 ** Injectio Adrenalini
 * Injectio Aminophyllini
 ** Injectio Apomorphini Hydrochloridi
 ** Injectio Atropini Sulfatis
 ** Injectio Bismuthi et Kalii Tartratis
 * Injectio Bismuthi Subsalcylatis
 * Injectio Calcii Gluconatis
 Injectio Carbacholi
 * Injectio Coffeini et Natrii Benzoatis
 ** Injectio Coffeini et Natrii Salicylatis
 ** Injectio Desoxycortoni Acetatis
 * Injectio Dextrosi
 Injectio Diethylstilboestrolis
 Injectio Digoxini
 * Injectio Dihydrostreptomycini
 ** Injectio Dimercaprolis
 * Injectio Emetini Hydrochloridi
 * Injectio Ergometrini Maleatis
 Injectio Ergotamini Tartratis
 * Injectio Heparini
 Injectio Histamini Phosphatis
 Injectio Hydromorphoni Hydrochloridi
 ** Injectio Hyoscini Hydrobromidi
 Injectio Lanatosidi C
 ** Injectio Lobelini Hydrochloridi
 Injectio Menadioni
 Injectio Mepacrini Methanosulfonatis
 * Injectio Mersalyli et Theophyllini
 * Injectio Morphini
 Injectio Natrii Salicylatis
 * Injectio Neostigmini Methylsulfatis
 * Injectio Nicethamidi
 * Injectio Nicotinamidi
 Injectio Oestradioli Benzoatis
 Injectio Oestroni
 Injectio Ouabaini
 * Injectio Papaverini Hydrochloridi
 * Injectio Pentetrazoli
 * Injectio Pethidini Hydrochloridi
 Injectio Phenobarbitali Natrici
 ** Injectio Physostigmini Salicylatis
 ** Injectio Physostigmini Sulfatis
 * Injectio Picrotoxini
 ** Injectio Procaini Benzylpenicillini Aquosa
 ** Injectio Procaini Benzylpenicillini Oleosa
 * Injectio Procaini Hydrochloridi
 * Injectio Progesteroni
 ** Injectio Riboflavini
 * Injectio Stibii et Kalii Tartratis
 * Injectio Stibii et Natrii Tartratis
 * Injectio Stibii et Natrii Thioglycollatis
 * Injectio Stibopheni
 Injectio Streptomycini et Calcii Chloridi
 Injectio Streptomycini Hydrochloridi
 Injectio Streptomycini Sulfatis
 ** Injectio Strychnini Nitratis
 * Injectio Sulfadiazini Natrici
 * Injectio Sulfamerazini Natrici
 * Injectio Sulfathiazoli Natrici
 Injectio Testosteroni Propionatis
 Injectio Tetracaini Hydrochloridi
 Injectio Tryparsamidi
 Injectio Tubocurariini Chloridi
 Isoprenalini Hydrochloridum
 Isoprenalini Sulfas
 ** Methadoni Hydrochloridum
 Methioninum
 ** Metoponi Hydrochloridum

* Completed and ready for printing.

** Discussed at the eighth session.

- | | |
|--|--|
| * Natrii Chloridum | Solutio Natrii Lactatis Composita
(Synonym : Ringer's Lactate Solution) |
| Natrii Metabisulfis | |
| Natrii Nitris | * Streptomycini et Calcii Chloridum |
| ** Natrii Para-aminosalicylas | * Streptomycini Hydrochloridum |
| Oleum Hydnocarp | * Streptomycini Sulfas |
| ** Oxophenarsini Hydrochloridum | Streptomycinum |
| ** Oxycodoni Hydrochloridum | ** Suraminum Natricum |
| Pentamidinum | ** Thyroidea |
| Phenylmercuri Boras | * Tinctura Aconiti |
| Phenylmercuri Nitras | * Tinctura Belladonnae |
| * Procaini Benzylpenicillinum | * Tinctura Colchici |
| Profenamini Hydrochloridum | * Tinctura Hyoscyami |
| Promethazini Hydrochloridum | * Tinctura Ipecacuanhae |
| * Propylthiouracilum | * Tinctura Scillae |
| Solutio Acidi Citratis Dextrosi Anticoagulans | * Tinctura Stramonii |
| Solutio Natrii Chloridi Composita
(Synonym : Ringer's Solution) | * Tinctura Strychni |
| Solutio Natrii Chloridi Isotonica | Trihexyphenydyllum |
| Solutio Natrii Citratis Anticoagulans | Tripelennamini Hydrochloridum |
| | * Tubocurariini Chloridum |
| | Tyrothricinum |

Appendices

- | | |
|---|--|
| Biological Assay of Benzylpenicillinum | * Iniectiones |
| * Biological Assay of Dihydrostreptomycinum | Pyrogen Test |
| * Biological Assay of Gonadotrophinum Chorionicum | Reagents and Test Solutions |
| * Biological Assay of Gonadotrophinum Sericum | Sugar-Coated Tablets |
| * Biological Assay of Streptomycinum | ** Table of Usual Doses of Drugs for Children |
| * Biological Assay of Tubocurariini Chloridum | Test for Freedom from Abnormal Toxicity of Dimercaprolum |
| * Compressi | * Test for Sterility for Streptomycinum |
| * Determination of Methoxyl | Tests for Sterility |
| | * Tincturae |

* Completed and ready for printing.

** Discussed at the eighth session.

Annex 3

SUBCOMMITTEE ON NON-PROPRIETARY NAMES

Report on the Second Session

Geneva, 30 April–1 May 1951

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1. Protection of international non-proprietary names	27
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SUBCOMMITTEE ON NON-PROPRIETARY NAMES

Second Session

Members :

Dr. H. Baggesgaard Rasmussen, Professor of Organic Chemistry, Royal Danish School of Pharmacy, Copenhagen, Denmark; Member of the Danish Pharmacopoeia Commission

Dr. C. H. Hampshire, formerly 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 de la Pharmacopée française (*Vice-Chairman*)

Dr. L. C. Miller, Director of Revision of the Pharmacopoeia of the United States of America, New York, N.Y., USA

Secretary :

P. Blanc, Chief, Pharmaceutical Section, WHO

The report on the second session of this subcommittee was originally issued in mimeographed form as document WHO/Pharm/151, 23 May 1951.

SUBCOMMITTEE ON NON-PROPRIETARY NAMES

Report on the Second Session¹

The Subcommittee on Non-Proprietary Names held its second session in Geneva, on 30 April and 1 May 1951.

1. Protection of International Non-Proprietary Names

The subcommittee noted that the Executive Board had adopted the report on the first session² and had requested the Director-General to continue the study of the question of the selection and introduction of international non-proprietary names of drugs which might later be inserted in the *Pharmacopoea Internationalis* (Ph.I.), and to explore the possibilities offered by the International Union for the Protection of Industrial Property. The international non-proprietary names selected at the first session had been forwarded to the Member States with a request that they should be granted protection in the different countries and accepted as official international non-proprietary (generic, common) names. Member States were also requested to grant similar protection to other names which might later be selected by the subcommittee. The subcommittee was informed that these names would be communicated also to all national pharmacopoeial authorities and to all organizations, such as the World Medical Association and the International Pharmaceutical Federation, in a position to help in the introduction of international non-proprietary names throughout the world.

Special attention was given to the means of expediting the selection by the subcommittee and the introduction of international non-proprietary

¹ The Executive Board, at its eighth session, adopted the following resolution :
The Executive Board

1. NOTES the report on the proceedings of the second session of the Subcommittee on Non-Proprietary Names of the Expert Committee on the International Pharmacopoeia ;

2. THANKS the members of the subcommittee for their work, and

3. AUTHORIZES publication of the report.

(Resolution EB8.R42, *Off. Rec. World Hlth Org.* 36. 14)

² Resolution EB7.R73, *Off. Rec. World Hlth Org.* 32, 30

names. The subcommittee noted that certain countries made it compulsory for the manufacturers to sell drugs under a non-proprietary name; it was therefore essential that international non-proprietary names should be selected rapidly and used as such.

The subcommittee noted the correspondence which had been exchanged with different organizations since the last session and had led to their agreement with the principles, adopted by the Third World Health Assembly,³ as given in Appendix 1,⁴ and voiced its appreciation of the collaboration already secured from interested countries, particularly France, the United Kingdom, and the USA.

The subcommittee noted the success achieved by Dr. Miller in his inquiries made to the American Drug Manufacturers Association and the Federal Food and Drug Administration, and asked him to continue his efforts. The subcommittee recommended that the Director-General write a letter to the Federal Food and Drug Administration to thank them for their proposal to insert a request from WHO for information on new drugs in their correspondence with manufacturers.

It was considered that manufacturers might be asked to submit information on new drugs to be named, with proposals for names, directly to the members of the subcommittee and to WHO to facilitate the choice of an international non-proprietary name with the least possible delay. The subcommittee noted that the French pharmacopoeia commission would likewise submit their proposed names before officially selecting them as national non-proprietary names. It was reported that a similar arrangement could probably be made with the Scandinavian Pharmacopoeia Council.

The subcommittee noted that one of the major difficulties in selecting names lay in making the necessary search in the different countries to ascertain that a proposed name was not already a registered name in some countries. The subcommittee appreciated the fact that the International Union for the Protection of Industrial Property had agreed to help in the search for names registered internationally by countries which were signatories to the Union Convention of Paris, 20 March 1883, for the Protection of Industrial Property, as revised at Brussels, 14 December 1900, at Washington, 2 June 1911, at The Hague, 6 November 1925, and in London, 2 June 1934. Moreover, it was regarded as highly desirable that the assistance of the combined Trade-Mark Bureau in Washington should be secured in order to ascertain whether any of the proposed names were already registered.

³ Resolution WHA3.11, *Off. Rec. World Hlth Org.* 28, 19

⁴ See page 29.

2. International Non-Proprietary Names

The subcommittee considered the proposals for international non-proprietary names of some of the drugs which are covered by the *Pharmacopoea Internationalis*, first edition, volume II, as well as other drugs, and adopted the names given in Appendix 2.

3. Date of Next Session

The subcommittee recommended that it should meet for a two-day session immediately after the ninth session of the Expert Committee on the International Pharmacopoeia.

Appendix 1

GENERAL PRINCIPLES FOR A SYSTEM OF INTERNATIONAL NON-PROPRIETARY NAMES

In order to avoid the difficulties which arise from the multiplicity of names for the same medicinal substance, WHO should adopt the practice of recognizing, as approved names, certain non-proprietary names which may be used freely by manufacturers.

The intention is that, if any of the drugs to which those approved names are applied should eventually be described in the *Pharmacopoea Internationalis* (Ph.I.) or in a national pharmacopoeia, the approved name should be its official title. On the other hand, the recognition of an approved name does not imply that the substance will necessarily be included in the Ph.I.

Requests from manufacturers and others for approved names for products which appear likely to come into established use might be considered. Such requests should be accompanied by:

(a) reports of pharmacological and clinical investigations on the drug concerned; and

(b) a number of suggestions for a suitable name, having regard to the need to avoid similarity to existing trademarks and other current names.

If a manufacturer should desire to issue under a proprietary name a drug for which an approved name has been provided, it is recommended that the label should bear the approved name of the substance.

The following general principles are stated for guidance in devising new names:

(1) Names should, preferably, be free from any anatomical, physiological, pathological, or therapeutic suggestion.

(2) An attempt should first be made to form a name by the combination of syllables from the scientific chemical name, in such a way as to indicate the significant groupings of the compound.

(3) Names should, in general, not exceed four syllables.

(4) Names should be distinctive in sound and spelling, and should not be liable to confusion with names already in use.

(5) Names which are difficult to pronounce or to remember should be avoided.

(6) The addition of a terminal capital letter or number should be avoided.

(7) Names already used in the national pharmacopoeias or officially adopted in any country, or which are included in *New and Nonofficial Remedies*, should receive preferential consideration.

(8) The following terminations should be used :

<i>Latin</i>	<i>English</i>	
-inum	-ine	for alkaloids and organic bases
-inum	-in	for glycerides and neutral principles
-osidum	-oside	for glycosides
-olum	-ol	for alcohols and phenols (-OH group)
-alum	-al	for aldehydes
-onum	-one	for ketones and other substances containing the CO group
-enum	-ene	for unsaturated hydrocarbons
-anum	-ane	for saturated hydrocarbons

Appendix 2

INTERNATIONAL NON-PROPRIETARY NAMES

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Acetaminosalolum Acetaminosalol Acétaminosalol	acetyl-4-aminophenyl salicylate
Acidum Dehydrocholicum Dehydrocholic Acid Acide déhydrocholique	
Acriflavini Chloridum Acriflavinium Chloride Chlorure d'acriflavinium	mixture of the hydrochlorides of 3,6-diamino-10-methylacridinium chloride and 3,6-diamino-acridine
Adipheninum Adiphenine Adiphénine	diethylaminoethyl ester of diphenylacetic acid
Aethyldicoumarolum Ethyldicoumarol Ethyldicoumarol	ethyl ester of bis-(4-hydroxycoumarin)-3,3'-acetic acid
Allobarbitalum Allobarbital Allobarbital	5,5-diallylbarbituric acid

<i>International non-proprietary name (Latin, English, French)</i>	<i>Chemical name or description</i>
Aureomycinum Aureomycin Auréomycine	
Bacitracinum Bacitracin Bacitracine	
Benzalkonii Chloridum Benzalkonium Chloride Chlorure de benzalkonium	mixture of alkylbenzyltrimethylammonium chlorides
Benzethonii Chloridum Benzethonium Chloride Chlorure de benzéthonium	benzyltrimethyl- <i>p</i> -(1,1,3,3-tetramethylbutyl)phenoxyethoxyethylammonium chloride
Benzylsulfamidum Benzylsulfamide Benzylsulfamide	4-benzylaminophenylsulfonamide
Biotinum Biotin Biotine	
Cetobemidonum Ketobemidone Cétobémidone	4- <i>m</i> -hydroxyphenyl-1-methyl-4-propionylpiperidine
Chlorcyclizinii Chloridum Chlorcyclizinium Chloride Chlorure de chlorcyclizinium	(±) 1-(<i>p</i> -chlorobenzhydryl)4-methylpiperazinium chloride
Cinchocainii Chloridum Cinchocainium Chloride Chlorure de cinchocaïnium	hydrochloride of the β-diethylaminoethylamide of 2-butyloxycinchonic acid
Cinchophenum Cinchophen Cinchophène	2-phenylquinoline-4-carboxylic acid
Cocarboxylasum Cocarboxylase Cocarboxylase	pyrophosphoric ester of thiamine
Cortisonum Cortisone Cortisone	11-dehydro-17-hydroxycorticosterone
Cyanocobalaminum Cyanocobalamin Cyanocobalamine	vitamin B ₁₂
Cyclobarbitalum Cyclobarbital Cyclobarbital	5-(1-cyclohexenyl)5-ethylbarbituric acid
Decamethonium Decamethonium Décaméthonium	decamethylene-1,10-bis(trimethylammonium)

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Diaphenylsulfonum Diaphenylsulfone Diaphénylsulfone	4,4'-diaminodiphenylsulfone
Diethazinum Diethazine Diéthazine	<i>N</i> -diethylaminoethylphenothiazine
Diodonum Diodone Diodone	diethanolamine 3,5-diiodo-4-pyridone- <i>N</i> -acetate
Disulfiramum Disulfiram Disulfirame	tetraethylthiuram disulfide
Eucatropinum Eucatropine Eucatropine	4-hydroxy-1,2,2,6-tetramethylpiperidine phenylglycollate
Fenethazinum Fenethazine Fénéthazine	<i>N</i> -(2-dimethylamino-1-ethyl) phenothiazine
Gramicidinum Gramicidin Gramicidine	
Heptaminolum Heptaminol Heptaminol	2-amino-6-methylheptan-6-ol
Hexamethonium Hexamethonium Hexaméthonium	hexamethylene-1,6-bis(trimethylammonium)
Hexoestrolum Hexoestrol Hexœstrol	3,4-di-(<i>p</i> -hydroxyphenyl) <i>n</i> -hexane
Hydroxyamphetaminii Bromidum Hydroxyamphetaminium Bromide Bromure d'hydroxyamphétaminium	1- <i>p</i> -hydroxyphenyl-2-aminopropane hydrobromide
Ichthammolum Ichthammol Ichthammol	ammonium ichthyosulfonate
Iodophthaleinum Natricum Iodophthalein Sodium Iodophtaléine sodique	disodium salt of tetraiodophenolphthalein
Isoprenalinum Isoprenaline Isoprénaline	1-(3',4'-dihydroxyphenyl)-2-isopropylamino-ethanol
Khellinum Khellin Khelline	5,8-dimethoxy-3-methyl-6,7-furano-chromone, extracted from the fruits of <i>Ammi visnaga</i> (L.) Lam.

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Lidocainum Lidocaine Lidocaïne	diethylamino-2,6-dimethylacetanilide
Mafenidum Mafenide Mafénide	4-aminomethylphenylsulfonamide
Menadioni Natrii Bisulfis Menadione Sodium Bisulfite Bisulfite sodique de ménadione	2-methyl-1,4-naphthoquinone sodium bisulfite
Mephenesinum Mephenesin Méphénésine	1,2-dihydroxy-3-(2'-methylphenoxy)propane
Meralluridum Meralluride Méralluride	mixture of methoxyoxymercuripropylsuccinylurea and theophylline
Mercurophyllinum Mercurophylline Mercurophylline	mixture of the sodium salt of the β -methoxy- γ - hydroxymercuripropylamide of trimethylcyclo- pentanedicarboxylic acid and theophylline
Methacholinii Chloridum Methacholinium Chloride Chlorure de méthacholinium	acetyl- β -methylcholinium chloride
Methamphetaminii Chloridum Methamphetamine Chloride Chlorure de méthamphétaminium	(+) 1-phenyl-2-methylaminopropane hydrochloride
Methapyrilenum Methapyrilene Méthapyrilène	<i>N,N</i> -dimethyl- <i>N'</i> -(2-pyridyl)- <i>N'</i> -(2-thenyl) ethylenediamine
Methenaminum Methenamine Méthénamine	hexamethylenetetramine
Methiodalum Natricum Methiodal Sodium Méthiodal sodique	sodium iodomethanesulfonate
Naphazolinum Naphazoline Naphazoline	2-(1-naphthylmethyl) imidazoline
Natrii Aurothiomas Sodium Aurothiomalate Aurothiomalate de sodium	mainly the sodium salt of aurothiomalic acid
Natrii Stibogluconas Sodium Stibogluconate Stibogluconate de sodium	sodium antimonylgluconate
Neocinchophenum Neocinchophen Néocinchophène	ethyl 6-methyl-2-phenylquinoline-4-carboxylate

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Neomycinum Neomycin Néomycine	
Nitrofuralem Nitrofuralem Nitrofuralem	5-nitro-2-furaldehyde semicarbazone
Oxapropanii Iodidum Oxapropanium Iodide Iodure d'oxapropanium	1-dimethylaminomethylene-2,3-dioxypropane iodomethylate
Paramethadionum Paramethadione Paraméthadione	3,5-dimethyl-5-ethyloxazolidine-2,4-dione
Pentamethonium Pentamethonium Pentaméthonium	pentamethylene-1,5-bis(trimethylammonium)
Pentobarbitalum Pentobarbital Pentobarbital	5-ethyl-5-(1-methylbutyl) barbituric acid
Phenadoxonum Phenadoxone Phénadoxone	6-morpholino-4,4-diphenylheptan-3-one
Phenicarbazidum Phenicarbazide Phénicarbazide	phenylsemicarbazide
Pheniodolum Naticum Pheniodol Sodium Phéniodol sodique	sodium α -phenyl- β -(4-hydroxy-3,5-diiodophenyl) propionate
Phenothiazinum Phenothiazine Phénothiazine	
Pholedrinii Sulfas Pholedrinium Sulfate Sulfate de pholédrium	β -(<i>p</i> -hydroxyphenyl) isopropylmethylammonium sulfate
Piperocainii Chloridum Piperocainium Chloride Chlorure de pipérocaïnium	3-benzyloxy-1-(2-methylpiperidino) propane hydrochloride
Polyvidonum Polyvidone Polyvidone	polyvinylpyrrolidone
Pyridoxinii Chloridum Pyridoxinium Chloride Chlorure de pyridoxinium	4,5-di(hydroxymethyl)-3-hydroxy-2-methyl- pyridinium chloride
Secretinum Secretin Sécrétine	hormone of the duodenal mucosa which activates the pancreatic secretion and lowers the blood- sugar level

<i>International non-proprietary name (Latin, English, French)</i>	<i>Chemical name or description</i>
Stibosaminum Stibosamine Stibosamine	diethylamine <i>p</i> -aminophenylantimonate
Sulfacetamidum Sulfacetamide Sulfacétamide	<i>p</i> -aminophenylsulfacetamide
Sulfachrysoïdinum Sulfachrysoïdine Sulfachrysoïdine	diaminosulfonamidocarboxyazobenzene
Sulfadimidinum Sulfadimidine Sulfadimidine	2-sulfanilamido-4,6-dimethylpyrimidine
Sulfapyridinum Sulfapyridine Sulfapyridine	2-sulfanilamidopyridine
Sulfathiourea Sulfathiourea Sulfathio-urée	<i>p</i> -aminophenylsulfonylthiourea
Sulfogaiacolum Sulfogaiacol Sulfogaiacol	potassium guaiacolsulfonate
Tetrylammonii Bromidum Tetrylammonium Bromide Bromure de tétrylammonium	tetraethylammonium bromide
Thioacetazonum Thioacetazone Thioacétazone	4-acetamidobenzaldehyde thiosemicarbazone
Thiomersalum Thiomersal Thiomersal	sodium ethylmercurithiosalicylate
Tolazolinum Tolazoline Tolazoline	2-benzylimidazoline
Trimethadionum Trimethadione Triméthadione	3,5,5-trimethyloxazolidine-2,4-dione

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