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WORLD HEALTH ORGANIZATION
TECHNICAL REPORT SERIES

No. 50

EXPERT COMMITTEE
ON THE
INTERNATIONAL PHARMACOPOEIA

Ninth Report

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WORLD HEALTH ORGANIZATION
PALAIS DES NATIONS

GENEVA

MAY 1952

EXPERT COMMITTEE ON THE INTERNATIONAL PHARMACOPOEIA

Ninth Session

Geneva, 29 October - 3 November 1951

Members :

- Dr. H. Baggesgaard Rasmussen, Professor of Organic Chemistry, Royal Danish School of Pharmacy, Copenhagen, Denmark ; Member of the Danish Pharmacopoeia Commission and of the Scandinavian Pharmacopoeial Council
- Dr. T. Canbäck, Director, Pharmaceutical Control Laboratory, Stockholm, Sweden ; Vice-Chairman, Swedish Pharmacopoeia Commission ; Member of the Scandinavian Pharmacopoeial Council
- 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 (*Vice-Chairman*)
- 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. B. Mukerji, Director, Central Drug Research Institute, Lucknow, and Central Drugs Laboratory, Calcutta, India ; Joint Secretary, Co-ordination Committee, Indian Pharmacopoeia
- Dr. D. van Os, Professor of Pharmacy and Toxicology, University of Groningen, Netherlands ; Chairman, Netherlands Pharmacopoeia Commission

Secretary :

P. Blanc, Chief, Pharmaceutical Section, WHO

The report on the ninth session of this committee was originally issued in mimeographed form as document WHO/Pharm/175, 15 November 1951.

EXPERT COMMITTEE

ON THE

INTERNATIONAL PHARMACOPOEIA

Ninth Report ¹

The Expert Committee on the International Pharmacopoeia held its ninth session in Geneva from 29 October to 3 November 1951.

The Assistant Director-General, Department of Central Technical Services, opened the ninth session of the Expert Committee on the International Pharmacopoeia. Referring to the publication of volume I of the *Pharmacopoea Internationalis* (Ph.I.), he expressed the thanks of WHO, and stressed the importance of preparing volume II so that it would be available together with volume I for adoption by such countries as had no national pharmacopoeia or whose pharmacopoeia was out-of-date. He thanked the members of the committee who had presented it in September 1951 to the XIVth General Assembly of the International Pharmaceutical Federation in Rome. The preparation of lists of synonyms for the drugs included in volume I and volume II of the Ph.I. would be continued and arrangements would be made concerning the Agreement revising the Agreement respecting the Unification of Pharmacopoeial Formulas for Potent Drugs, signed at Brussels on 20 August 1929. The committee would also study the selection and protection of international non-proprietary names, consider the collection on a worldwide scale of information on pharmaceutical preparations, and prepare for a special session in 1953 on the control of pharmaceutical preparations.

The Director of the Division of Therapeutic Substances thanked the members and in particular the Chairman of the committee for all the work done in the preparation of volume I and volume II of the Ph.I.

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

1. NOTES the report of the Expert Committee on the International Pharmacopoeia on its ninth session, and the report of the Subcommittee on Non-Proprietary Names on its third session;
 2. THANKS the members of the committee and of the subcommittee for their work, and
 3. AUTHORIZES publication of these reports in one volume.
- (Resolution EB9.R93, *Off. Rec. World Hlth Org.* 40, 33)

1. Resolutions Adopted at the Fourth World Health Assembly and at the Eighth Session of the Executive Board

The committee noted that the Fourth World Health Assembly had adopted a resolution giving approval to the taking over by WHO of the functions of the Permanent International Pharmacopoeia Secretariat, previously entrusted to the Belgian Pharmacopoeia Commission, with effect from 1 January 1951.²

The committee further noted that the Executive Board at its eighth session had authorized the publication of the report on the eighth session of the Expert Committee on the International Pharmacopoeia and of the report on the second session of the Subcommittee on Non-Proprietary Names,³ and had approved the recommendation that the Director-General should study the measures to be taken for protecting international non-proprietary names and prepare regulations to ensure their legal protection.⁴ The Executive Board had also approved a resolution inviting the Director-General to prepare regulations, to be adopted in accordance with Article 21 (d) of the Constitution of WHO, in which the provisions of the *Pharmacopoea Internationalis* would be embodied and which would replace the 1929 Brussels Agreement.⁵

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

The committee was pleased to note that volume I of the Ph.I. was published on 30 October 1951, both English and French editions being available simultaneously. The Spanish translation was being made and would appear later. This first edition consisted of 3,000 copies in English and 2,500 in French. A further printing of 3,000 copies in English had already been requested to cope with the demand. Publicity material and copies for review had been distributed to the technical press. For countries wishing to adopt the work as their national pharmacopoeia special low rates for bulk orders of the book could be arranged by WHO. The Division of Public Information reported that publicity for the general public had been prepared in the form of a worldwide press release and distribution of the *WHO Newsletter*.

² Resolution WHA4.13, *Off. Rec. World Hlth Org.* 35, 21

³ Resolutions EB8.R39, EB8.R42, *Off. Rec. World Hlth Org.* 36, 12, 14

⁴ Resolution EB8.R41, *Off. Rec. World Hlth Org.* 36, 13

⁵ Resolution EB8.R40, *Off. Rec. World Hlth Org.* 36, 12

The committee noted that copies would be sent to national pharmacopoeial authorities and public-health administrations through the governments of Member States with a letter from the Director-General, and that on request to WHO further copies could be made available to members of the committee for them to give to people who had provided them with assistance in various aspects of their work in preparing the Ph.I. A copy of volume I would be sent to Professor L. van Itallie with a letter conveying the best wishes of the committee on the occasion of the publication of the Ph.I. which owed much to his efforts in the early days.

The committee noted that some comments on volume I were being received and it was agreed that such comments would be referred to members for consideration at the next session.

It was stressed that if any country, or private or public body, wished to publish the work as the *Pharmacopoea Internationalis* or as a translation of it the responsibility would rest with WHO which would decide whether authorization should be granted and would control the translation.

2.1 *List of synonyms of drugs included in the Pharmacopoea Internationalis, volume I*

The committee was informed that as regards the USA the list could now be published without indicating by any distinguishing marks what names were trademarked in certain countries. It was agreed that Professor Hazard and the Secretary of the committee should hold a meeting with the French *Chambre syndicale nationale des Fabricants de Produits pharmaceutiques* which had expressed the wish that a distinction between trademarks and non-proprietary names should be made. As soon as the members of the committee had finished checking the list previously circulated the list could be completed by WHO and published as a supplement to the *Bulletin of the World Health Organization*.

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

Following a report submitted by the Chief of the Legal Office, and after discussion of the matter,

The Expert Committee on the International Pharmacopoeia,

Considering paragraph 3 of resolution EB8.R40,⁶ by which the Director-General was requested by the Executive Board to prepare

⁶ *Off. Rec. World Hlth Org.* 36, 12

regulations, to be adopted in accordance with Article 21 (*d*) of the Constitution of WHO, in which the provisions of the *Pharmacopoea Internationalis* would be embodied and which would replace the 1929 Brussels Agreement ;

Being of opinion that it would suffice for the time being for the Brussels Agreements of 1906 and 1929 to be terminated, the *Pharmacopoea Internationalis* consequently retaining its present status as a recommendation by the World Health Assembly,

NOTES the text of a draft Protocol⁷ for the termination of these Agreements prepared by the Director-General to this end.

4. Preparation of the Pharmacopoea Internationalis, First Edition, Volume II

The committee noted that 134 monographs on pharmaceutical preparations and 9 appendices covering analytical methods, etc., had been completed either at the eighth session, or subsequently by the Chairman of the committee and by WHO. The titles of these monographs and appendices are given in Annex 2 of this report.⁸ It was recommended that this material be printed in galley proof forthwith in order to speed up the work and make it possible to publish volume II in 1952. When necessary separate blocks corresponding to the usual practice of each language should be used for the printing of graphic formulae. The committee noted that a programme of publication is to be prepared by the Division of Editorial and Reference Services and that it is expected that volume II will be published at the end of 1952. The French and English editions should be published simultaneously, while there would be a certain delay in producing the Spanish edition, which is to be a translation from the final English and French texts ; however, every effort would be made to reduce this delay as much as possible. Professor Hazard indicated that he would continue his collaboration on the preparation of the text of the French edition.

4.1 Consideration of draft monographs

Of a total of 39 monographs requiring close study and extended discussion by the committee, 15 were completed save for minor details which would be supplied in correspondence on the basis of the principles discussed at this session. It was agreed that a serious effort would be made to complete as many as possible of the remaining monographs in an advanced stage

⁷ See Annex 3, page 23.

⁸ See page 20.

of preparation so that they may be included in volume II. It was agreed, however, that, rather than delay publication of volume II, all monographs not completed in their entirety by the next session must be held over for the future.

The completed monographs were: Adrenalini Bitartras, Aethanolum, Aethanolum Absolutum, Aethanolum Dilutum, Antazolini Hydrochloridum, Calcii Saccharas, Chlorobutanolum, Chlorobutanolum Hydratum, Glycerolum, Glycerolum Dilutum, Injectio Adrenalini Bitartratis, Injectio Dimercaproli, Phenylhydrargyri Boras, Phenylhydrargyri Nitras, and Podophylli Resina.

The discussion of the assay of Adrenalini Bitartras brought to notice the fact that a new chemical procedure has recently been published; members of the committee undertook to compare it with earlier methods which have generally been regarded as not sufficiently specific for pharmacopoeial purposes.

With regard to Digitoxosidum the question of the international nomenclature for this general class of compounds was referred to the Committee on Nomenclature of the International Union of Pure and Applied Chemistry. Further, to avoid the necessity for biological assay of this highly potent cardiac drug, special precautions were agreed upon for determining the melting-range and other physical and chemical characters.

Because Glycerolum and Aethanolum are derived from a wide variety of natural sources in different parts of the world, as well as synthetically, the committee felt obliged to provide a larger number of tests than usual to ensure the degree of purity required for pharmaceutical purposes, especially since these liquids are used in large quantities as vehicles for oral preparations.

Podophylli Resina had been included at the request of the Expert Committee on Venereal Infections and Treponematoses. Inasmuch as to date the clinical studies in the clearing of venereal warts appear to have involved only the resin from *Podophyllum peltatum* the Ph.I. standards apply to this product. While the committee felt obliged to exclude the resin from *Podophyllum Emodi*, a plant native to India, for want of information on its efficacy for the purposes stated, the way was left open to include it at a later date.

4.2 *Cardiolipin and lecithin*

As decided at the seventh session of the committee,⁹ a special article on cardiolipin and purified lecithin, two agents of great importance in the serological diagnosis of syphilis, is being incorporated in the Ph.I.

⁹ *World Hlth Org. techn. Rep. Ser.* 1951, 35, 10

This is being done at the request of the Subcommittee on Serology and Laboratory Aspects of the Expert Committee on Venereal Infections and Treponematoses, to ensure worldwide dissemination of information on the necessary reagents and the technical details of this test.

Inasmuch as the Expert Committee on the International Pharmacopoeia has been responsible only for the chemical tests on cardiolipin and purified lecithin, this fact would be noted in the preface. The committee noted the considerable work on the physico-chemical tests done by the working-group and wished to thank them for it.

The committee referred the matter to the Expert Committee on Biological Standardization, which had agreed to provide the description of the serological tests.

4.3 *Preparations of human blood*

The committee noted that a number of national pharmacopoeias are now including several preparations of human blood. It was agreed that a study should be made, in collaboration with the Expert Committee on Biological Standardization, in order to determine which preparations should be included in the Ph.I., taking into account the various pharmacopoeial problems of these biological preparations.

4.4 *Suture materials*

The committee noted that much information regarding standards required for surgical suture materials had been received from manufacturers in various countries and examined by the working-group, which reported on the subject, stressing the great difficulty but equally great importance of completing the work.

4.5 *Graphic formulae*

The committee thanked Professor Baggesgaard Rasmussen for providing graphic formulae for volume II. It was decided that the graphic formulae of steroids should give an indication of stereo-isomerism.

4.6 *New methods of analysis*

At earlier sessions of the committee, the question had arisen as to how far new methods of analysis should be introduced into the Ph.I. Several members have already carried out basic experimental work and submitted reports. Some of these modern methods require expensive apparatus, not commonly found in pharmacies, such as the spectrophotometer, the fluorometer and the polarograph. The committee discussed in a very detailed manner whether these methods should really be used more

widely for pharmacopoeial purposes. It was noted that in many countries the pharmacist is required by law to control the drug dispensed and that therefore difficulties could arise if expensive instruments were required for pharmacopoeial assays. Nevertheless the committee decided that, while methods employing simpler equipment should be used as far as possible, new methods giving dependable results with a great saving in time ought to be introduced, even if such new instruments are required for these new methods. In certain instances alternative methods might be given.

It was found that the adaptation of these modern methods to pharmacopoeial purposes would require extensive laboratory work. Upon request from the committee some of the members are prepared to undertake such investigations. However, this will require trained laboratory men. The committee, therefore, recommends that favourable consideration be given to applications from members of the Expert Advisory Panel on the International Pharmacopoeia and others for grants to provide assistants and materials for investigations on the applicability of new methods of analysis to the monographs and appendices of the Ph.I.

Of the methods considered, investigation of the following should be given priority: colorimetry, column chromatography, paper chromatography, ion-exchange methods, microchemical reactions including preparation of derivatives on a microscale, melting-point determinations of derivatives and eutectic mixtures, the so-called "complexone" titration of certain metals, determination of refractive indices of solids, polarography, spectrophotometry, Karl Fischer method for the determination of water, and titration in non-aqueous liquids of weak bases and acids.

The committee felt that it would be a very progressive step to undertake work along these lines and would do much to enhance the scientific and practical value of the Ph.I.

4.7 *Table of Usual and Maximal Doses for Adults*

The committee noted that the draft Table of Usual and Maximal Doses for Adults had been submitted to the World Medical Association and that comments had been received. Professor Hazard undertook to revise the list in accordance with the comments submitted by the World Medical Association and the members of this and other expert committees and specialists throughout the world.

4.8 *Table of Doses for Children*

Professor Hazard reported that as far as possible the comments received from specialists in various countries who had reviewed the Table of Doses for Children, in so far as drugs included in volume I of the Ph.I. were

concerned, had been incorporated and that a preface explaining the principles used in determining the dosage had been added. A number of paediatricians had expressed approval of the work and the hope that it would soon be published. The Table of Doses for Children for drugs to be included in volume II of the Ph.I. was being completed, and it was hoped to have it checked by paediatricians on a worldwide scale and included in volume II of the Ph.I.

4.9 *Reagents and test solutions*

Professor van Os undertook to draft the appendix, and to ask the International Union of Pure and Applied Chemistry through its Commission for Standardization of the Purity of Chemical Products to provide specifications for the reagent chemicals required; such chemicals would be described as 'of reagent purity' until the complete specifications were available from the International Union of Pure and Applied Chemistry.

4.10 *Solutions employed in volumetric determinations*

The committee examined the draft prepared by the Secretary. A report will be prepared and submitted.

4.11 *Limit tests for arsenic, lead, heavy metals, and iron*

The committee noted the additional methods that it would be necessary to provide for the drugs to be included in volume II of the Ph.I. Draft appendices will be prepared and submitted.

4.12 *Quality of glass for ampoules*

Reports received from members of the committee were considered and three members agreed to prepare a draft appendix based on the general principles adopted by the committee.

4.13 *Other appendices*

It was agreed that the Karl Fischer method of the determination of water should be described in an appendix. A report is to be prepared on the test for the congealing-range of Chlorophenothanum Technicum.

4.14 *Isotonic solutions*

The committee noted the statement submitted for insertion in an appendix of volume II together with the graphs for the preparation of isotonic solutions.

4.15 *List of synonyms of drugs included in volume II*

It was agreed that WHO should prepare this list on the same lines as the list for volume I and that the work should be started as soon as possible so that the list could be published at about the same time as volume II.

4.16 *Future programme of publication*

The committee recommended that volume II of the Ph.I. should be published at the end of 1952. The first edition would then be completed, extended, and kept up to date by addenda to be issued in 1953 and in 1954. A complete revision would be made and published in 1955. Each of the foregoing should be published in English and in French simultaneously with a Spanish translation following with as little delay as practicable. Lists of synonyms should be published at the same time as, or as soon as possible after, the books to which they refer. The committee considered that in view of this programme of work two sessions of the committee each year would provide the minimum of meetings for carrying it out; in addition, much laboratory work and correspondence would have to be undertaken by members of the committee between sessions.

5. Relations with the WHO Expert Committee on Biological Standardization

The committee noted that texts of a number of biological tests required for inclusion in volume II had been received from the Expert Committee on Biological Standardization (toxicity test for dimercaprol, biological assay of tubocurarine chloride, sterility tests). The Expert Committee on Biological Standardization did not consider a toxicity test for oxophenarsine hydrochloride to be necessary. It was also noted that an international standard preparation of tubocurarine chloride was already available and that international standard preparations of dimercaprol and oxophenarsine hydrochloride would be made available shortly.

It was agreed that the Expert Committee on Biological Standardization should be asked to review the following drafts, together with comments from Dr. Miller, and give the final text for the following appendices for volume II: test for sterility of streptomycin, test for sterility of dihydrostreptomycin, test for sterility of penicillin, test for pyrogens. It was noted that the Expert Committee on Biological Standardization was studying hyaluronidase and taeniocidal drugs and would send reports in due course.¹⁰

¹⁰ See *World Hlth Org. techn. Rep. Ser.* 1952, 56.

6. Relations with the World Medical Association, the International Pharmaceutical Federation, and the International Labour Organisation

The committee noted that excellent and useful relations were being maintained with the World Medical Association on the subject of doses, and with the International Pharmaceutical Federation. The assistance of both organizations will be invaluable in the introduction of international non-proprietary names. A presentation of volume I of the Ph.I. had been made at the official inauguration of the XIVth General Assembly of the International Pharmaceutical Federation, September 1951, and members of the committee had given addresses on different aspects of the *Pharmacopoea Internationalis* and on international non-proprietary names.

The committee noted that a classification of toxic substances was to be prepared by the International Labour Organisation and that WHO had agreed to co-operate in the preparation of that particular part dealing with pharmaceuticals.

7. Fellowships

The committee noted that a number of fellowships had been granted during 1951 for the study of the control of pharmaceutical preparations and pharmacopoeial methods of assay in accordance with recommendations made previously. Many of the requests for fellowships were granted to persons in charge of control laboratories in their own country and were hence directly of help to national health administrations. It was recalled that such fellowships were available to all Member States and were not restricted to underdeveloped areas, and were primarily granted for the purpose of strengthening health services in the countries. Fellowships were normally granted to senior workers for two to four months, and for up to six months to one year to younger workers having generally at least two years' experience. In the case of undergraduates they were limited to countries which had no facilities for training their own people. Fellows were placed for study in laboratories selected from a list previously prepared with the assistance of the committee, which took the opportunity of revising this list of research and control institutions and of adding more names.

8. New Monographs and Appendices for the Pharmacopoea Internationalis and Addenda

8.1 Methods of selecting new substances

The committee considered methods by which the selection of new substances to be described in the Ph.I. and addenda could be made on as

broad and scientific a basis as possible. In view of the great importance attributed to this matter, it was agreed that lists could emanate from WHO and be passed to the Expert Advisory Panels on the International Pharmacopoeia and on Biological Standardization, the World Medical Association, the International Pharmaceutical Federation, and other organizations and specialists. Their comments, additions, or deletions would be taken into consideration by the committee which would undertake the study of the drugs found suitable for insertion in the Ph.I. Moreover, as has been done regularly in the past, other WHO expert committees would be asked to suggest new drugs for inclusion in the Ph.I.

8.2 *Collection of data on new drugs*

In order that WHO may initiate the work mentioned above, and also the work on the control of pharmaceutical specialities, the committee recommended that WHO should collect information such as pharmacological, clinical, and pharmaceutical data, details of assays, standards, and packaging for all new drugs on a worldwide basis. Such information, while essential for the work of the committee, would also be valuable to other expert committees and departments of WHO.

8.3 *Consideration of new substances*

The committee considered the lists of recent additions of new substances to national pharmacopoeias, as submitted by the Secretary, and made a selection to be studied for inclusion in addenda to the Ph.I.

The committee considered a proposition that the Ph.I. should include essential oils in general, and agreed that only essential oils of medicinal value should be included.

Proposals to include veterinary drugs and phytopharmaceutical preparations were deferred for later consideration.

9. **Preparation of a Session on the Control of Pharmaceutical Products**

The committee noted that the questionnaire sent out to Member States in September 1950, following a recommendation made at the sixth session of the committee,¹¹ had so far brought answers from 51 Member States, which had sent their regulations covering the control and sale of pharmaceuticals, and information on the pharmacopoeia used officially and on the methods used in the control of pharmaceuticals in their territory. The Chairman and the members indicated that conferences on a regional

¹¹ *World Hlth Org. techn. Rep. Ser.* 1950, 29, 15

basis had been held recently on the control of pharmaceuticals, particularly the First International Symposium on the Control of Pharmaceutical Specialities, held in Brussels, 15-17 June 1951, and the meeting of directors of national laboratories for the control of pharmaceuticals, in connexion with the XIVth General Assembly of the International Pharmaceutical Federation, held in Rome, 23-29 September 1951. Such work now done by groups of countries was proving extremely useful and should be integrated on a world basis under the aegis of WHO. It was reported at the last-mentioned meeting that the first needs were to establish definitions for such expressions as 'pharmaceutical specialities', 'control', 'drug', and to arrange for a system of certification of pharmaceuticals exported. In certain countries more than 40,000 specialities were sold on the market without a proper control being exercised, either on pharmaceuticals manufactured in the country or on imported pharmaceuticals.

The committee had previously expressed the wish that a conference on the control of pharmaceuticals be convened in the autumn of 1953, attended by representatives of national health administrations dealing with this subject.¹² However, budgetary reasons made it impossible to convene such a large conference; it would have to be replaced by a session of the committee which should consist of not less than fifteen members. It would evolve a set of definitions, principles, and recommendations on the control of pharmaceuticals which could be of direct help to countries who wished to initiate or better the control of pharmaceuticals in their territory in the general interest of public health and international commerce. Countries could adopt these definitions, principles, and recommendations according to the local situation and possibilities.

As a preparation for this special session the committee considered a list of subjects for which reports will be required from members of the Expert Advisory Panel on the International Pharmacopoeia and other specialists throughout the world. The more important subjects would be as follows:

- (1) Aims of the control of drugs
- (2) Definitions :
 - Pharmaceutical speciality, drug, control
 - Other definitions
- (3) Principles for setting up a system of control :
 - General plan for the introduction of a new pharmaceutical preparation
 - Responsibility of pharmacists
 - Methods of inspection of pharmacies and laboratories

¹² *World Hlth Org. techn. Rep. Ser.* 1951, 43, 17

Declaration of composition

Analytical, physical, chemical, and biological control

Export and import regulations (obligation of importer to produce a certificate from the authority of the country of origin showing that the drugs comply with the standards of the exporting country)

Selection of new specialities and approval for issue

(4) Labelling :

Definition of label, wrapper, package for inland and for export, inserts

Information to be put on the label—trademarks, non-proprietary names (national and international), manufacturer, lot number, date of manufacture, mark indicating year of issue, expiration date, directions for use

(5) Methods of analytical control :

Sampling, minimum and optimum equipment of control laboratories, unification of assay methods not included in the Ph.I., tests and assays on tablets, coated tablets, capsules, pills, suppositories, etc.

(6) Poisons :

Classification of poisons, dangerous drugs, etc.

Regulations for sale.

10. International Non-Proprietary Names for Drugs

10.1 *Consideration of the report on the second session of the Subcommittee on Non-Proprietary Names*

It was noted that the Executive Board had approved the report on the second session of the Subcommittee on Non-Proprietary Names.¹³

10.2 *Relations with the International Union for the Protection of Industrial Property*¹⁴

The committee made the following recommendation :

The Expert Committee on the International Pharmacopoeia,

Considering resolution EB8.R41¹⁵ concerning the protection of international non-proprietary names for drugs ;

¹³ Resolution EB8.R42, *Off. Rec. World Hlth Org.* 36, 14

¹⁴ The full title of this union is : United International Offices for the Protection of Industrial, Literary and Artistic Property.

¹⁵ *Off. Rec. World Hlth Org.* 36, 13

Noting the correspondence exchanged between the Director-General of the World Health Organization and the Director of the International Union for the Protection of Industrial Property concerning the eventual amendment of Article 6^{ter} of the International Convention which created the International Union for the Protection of Industrial Property signed at Paris on 20 March 1883, revised at Brussels on 14 December 1900, Washington on 2 June 1911, The Hague on 6 November 1925, and London on 2 June 1934 ;

Considering that the said International Union for the Protection of Industrial Property is the competent intergovernmental international organization in the matter of the protection of trade and related names,

RECOMMENDS that eventual measures for the legal protection in all countries of non-proprietary names for drugs adopted by the World Health Organization continue to be developed in co-operation with the International Union for the Protection of Industrial Property in order that they may be put into effect at such time as the Union Convention is revised.

The committee noted that, in accordance with resolution WHA3.11¹⁶ of the Third World Health Assembly, the Secretary, in collaboration with the Legal Office of WHO, was studying ways and means to protect the international non-proprietary names selected by the committee and the subcommittee with a view to preparing regulations under Article 21 (*d*) and (*e*) of the Constitution of WHO to ensure legal protection of the international non-proprietary names selected.

Meanwhile international non-proprietary names selected by the subcommittee and the committee were communicated to Member States and national pharmacopoeial authorities with a letter from the Director-General recommending that the names be officially recognized and adopted, and that Member States take action with a view to protecting these names against unauthorized use, particularly to prevent the granting of exclusive proprietary rights in these names to the manufacturers.

The committee was pleased to note that a number of countries had indicated that such action was being taken.

10.3 *List of international non-proprietary names*

The committee recommended that, for the convenience of physicians, pharmacists, and others who might use the international non-proprietary names, WHO should prepare a complete list of the international non-proprietary names selected by the subcommittee or created by the committee

¹⁶ *Off. Rec. World Hlth Org.* 28, 19

in preparing volume I and volume II of the Ph.I., and that this list should be published as a supplement to the *Bulletin of the World Health Organization*.

11. Name of Expert Advisory Panel

It was agreed that the name of the expert advisory panel should read :
Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

Annex 1

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

Professor Baggesgaard Rasmussen agreed :

- To provide an identification test for Digitoxosidum, depending on its solubility in chloroform
- To investigate the optical rotation of Calcii Saccharas and to supply a test for insertion in the monograph
- To present an appendix, prepared jointly with Professor Hazard and Dr. Canbäck, on the quality of glass for ampoules
- To investigate and report on new methods of analysis (column chromatography, ion exchange, titration in benzene and methanol, micro-preparation of derivatives, and melting-ranges of derivatives and eutectic mixtures)
- To check the list of synonyms of drugs included in volume I of the Ph.I.
- To provide the graphic formulae and chemical names for the monographs in volume II
- To provide graphic formulae for the lists of international non-proprietary names selected by the Subcommittee on Non-Proprietary Names

Dr. Canbäck agreed :

- To present a report, prepared jointly with Professor Heymans, on the assay of Adrenalini Bitartras
- To check the reaction of Injectio Adrenalini Bitartratis and to report on a suitable pH requirement to allow for the decrease in pH during storage
- To prepare, jointly with Professors Baggesgaard Rasmussen and Hazard, an appendix on the quality of glass for ampoules
- To present a draft appendix on the determination of water by the Karl Fischer method
- To investigate and report on new methods of analysis (complexone methods, refractive indices of solids, titration in acetic acid, and Karl Fischer method for the determination of water in inorganic and organic chemicals)
- To check the list of synonyms of drugs included in volume I of the Ph.I.

Professor Flück agreed :

- To recalculate the standard and assay equivalent for Calcii Saccharas
- To check the melting-range of Phenylhydrargyri Nitras and of Phenylhydrargyri Boras
- To report on the determination of water in crude drugs
- To investigate and report on new methods of analysis (paper chromatography, column chromatography on cellulose, and Karl Fischer method for the determination of water in crude drugs and galenicals)
- To check the list of synonyms of drugs included in volume I of the Ph.I.

Dr. Hampshire agreed :

- To report, jointly with Dr. Miller and Professor Heymans, on suitable preparations of human blood for inclusion in the Ph.I.
- To finalize by correspondence a number of monographs following on the lines adopted by the committee
- To report on Insulinum
- To check the list of synonyms of drugs included in volume I of the Ph.I.

Professor Hazard agreed :

- To investigate the test for identification of Digitoxosidum
- To consult, jointly with the Secretary, the French Chambre syndicale nationale des Fabricants de Produits pharmaceutiques
- To prepare, jointly with Professor Baggesgaard Rasmussen and Dr. Canbäck, an appendix on the quality of glass for ampoules
- To check the list of synonyms of drugs included in volume I of the Ph.I.
- To continue his work, jointly with Dr. Miller and Professor van Os, on suture materials
- To continue work on the Table of Doses for Children and the Table of Usual and Maximal Doses for Adults for volume II

Professor Heymans agreed :

- To report, jointly with Dr. Miller and Dr. Hampshire, on suitable preparations of human blood for inclusion in the Ph.I.
- To report, jointly with Dr. Canbäck, on the assay of Adrenalini Bitartras
- To check the list of synonyms of drugs included in volume I of the Ph.I.

Dr. Miller agreed :

- To report on the loss on drying of Adrenalini Bitartras
- To report on the dry-heat method of sterilization of Injectio Dimercapoli
- To submit a report, prepared jointly with Dr. Hampshire and Professor Heymans, on suitable preparations of human blood for inclusion in the Ph.I., and to provide the necessary draft monographs
- To check the list of synonyms of drugs included in volume I of the Ph.I.
- To present a report, prepared jointly with Professors Hazard and van Os, on suture materials

Dr. Mukerji agreed :

- To check the list of synonyms of drugs included in volume I of the Ph.I.

Professor van Os agreed :

- To write the complete article on cardiolipin and lecithin
 - To prepare the appendices on reagents and test solutions, solutions employed in volumetric determinations, limit test for arsenic, limit test for lead, and limit test for heavy metals
 - To investigate whether the method for the determination of congealing-range given in volume I of the Ph.I. was applicable to Chlorophenothanum Technicum and if necessary to supply a special method
 - To investigate new methods of analysis (colorimetry, micro-reactions for purity and identity of organic and inorganic chemicals)
 - To continue his work, jointly with Professor Hazard and Dr. Miller, on suture materials
 - To check the list of synonyms for drugs included in volume I of the Ph.I.
-

Annex 2

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

Monographs

Acetylcholini Hydrochloridum	Compressi Barbitali
Acidum Aminoaceticum	Compressi Barbitali Natrici
Acidum Folicum	Compressi Calcii Gluconatis
Acidum Lacticum	Compressi Calcii Lactatis
Acidum Para-aminosalicylicum	Compressi Carbacholi
Acidum Undecylenicum	Compressi Carbarsoni
Adrenalini Bitartras	Compressi Chiniofoni
Aethanolum	Compressi Chloroquini Diphosphatis
Aethanolum Absolutum	Compressi Codeini Phosphatis
Aethanolum Dilutum	Compressi Colchicini
Aethinyloestradiolum	Compressi Dicoumaroli
Aethylenediamini Hydras	Compressi Diethylstilboestrioli
Aethylis Hydnocarpas	Compressi Digitalis
Aethylurethanum	Compressi Digitoxosidi
Amodiaquini Hydrochloridum	Compressi Ephedrini Hydrochloridi
Antazolini Hydrochloridum	Compressi Ergometrini Maleatis
Aqua Destillata	Compressi Ergotamini Tartratis
Aqua pro Injectione	Compressi Ferrosi Sulfatis
Arterenoli Bitartras	Compressi Glyceryli Trinitratis
Aureomycini Hydrochloridum	Compressi Hydrargyri Subchloridi
Benzyloxyphenylpenicillinum	Compressi Hydromorphone Hydrochloridi
Bismuthi et Kalii Tartras	Compressi Hyoscini Hydrobromidi
Bismuthi Subnitras	Compressi Lanatosidi C
Calcii Saccharas	Compressi Menadioni
Cardiolipinum et Lecithinum	Compressi Mepacrini Hydrochloridi
Chloramphenicolum	Compressi Methyltestosteroni
Chlorobutanolum	Compressi Natrii Salicylatis
Chlorobutanolum Hydratum	Compressi Neostigmini Bromidi
Chlorocresolum	Compressi Nicotinamidi
Chlorophenothanum Technicum	Compressi Obducti
Cholini Hydrochloridum	Compressi Oestradioli
Compressi	Compressi Pethidini Hydrochloridi
Compressi Acidi Acetylsalicylici	Compressi Phenacetini
Compressi Acidi Ascorbici	Compressi Phenobarbitali
Compressi Aethisteroni	Compressi Phenobarbitali Natrici
Compressi Amidopyrini	Compressi Proguanili Hydrochloridi
Compressi Aminophyllini	Compressi Quinidini Sulfatis
Compressi Amphetamini Sulfatis	Compressi Quinini Sulfatis
Compressi Atropini Sulfatis	

Compressi Riboflavini	Injectio Lobelini Hydrochloridi
Compressi Santonini	Injectio Menadioni
Compressi Succinylsulfathiazoli	Injectio Mepacrini Methanosulfonatis
Compressi Sulfadiazini	Injectio Mersalyli et Theophyllini
Compressi Sulfaguanidini	Injectio Morphini
Compressi Sulfamerazini	Injectio Neostigmini Methylsulfatis
Compressi Sulfanilamidi	Injectio Nicethamidi
Compressi Sulfathiazoli	Injectio Nicotinamidi
Compressi Theobromini et Natrii Acetatis	Injectio Oestradioli Benzoatis
Conessini Hydrobromidum	Injectio Oestroni
Cyanocobalaminum	Injectio Ouabaini
Cyclopropanum	Injectio Papaverini Hydrochloridi
Dextranum Hydrolysatum	Injectio Pentetrazoli
Dichlorophenarsini Hydrochloridum	Injectio Pethidini Hydrochloridi
Digitoxosidum	Injectio Phenobarbitali Natrici
Dihydrostreptomycinum	Injectio Physostigmini Salicylatis
Dimercaprolum	Injectio Physostigmini Sulfatis
Diphenhydramini Hydrochloridum	Injectio PicROTOXINI
Gallamini Triethiodidum	Injectio Procaini Hydrochloridi
Glucosum	Injectio Progesteroni
Glycerolum	Injectio Riboflavini
Glycerolum Dilutum	Injectio Stibii et Kalii Tartratis
Gonadotrophinum Chorionicum	Injectio Stibii et Natrii Tartratis
Gonadotrophinum Sericum	Injectio Stibii et Natrii Thioglycollatis
Hexobarbitalum	Injectio Stibopheni
Hexobarbitalum Natricum	Injectio Streptomycini et Calcii Chloridi
Hydrocodoni Bitartras	Injectio Streptomycini Hydrochloridi
Hydromorphoni Hydrochloridum	Injectio Streptomycini Sulfatis
Injectiones	Injectio Strychnini Nitratris
Injectio Adrenalini Bitartratis	Injectio Sulfadiazini Natrici
Injectio Aminophyllini	Injectio Sulfamerazini Natrici
Injectio Apomorphini Hydrochloridi	Injectio Sulfathiazoli Natrici
Injectio Atropini Sulfatis	Injectio Testosteroni Propionatis
Injectio Bismuthi et Kalii Tartratis	Injectio Tetracaini Hydrochloridi
Injectio Bismuthi Subsaliicylatis	Injectio Thiopentali Natrici cum Natrii Carbonate
Injectio Calcii Gluconatis	Injectio Tryparsamidi
Injectio Carbacholi	Injectio Tubocurarini Chloridi
Injectio Coffeini et Natrii Benzoatis	Isoprenalini Hydrochloridum
Injectio Coffeini et Natrii Salicylatis	Isoprenalini Sulfas
Injectio Desoxycortoni Acetatis	Mepyraini Maleas
Injectio Diethylstilboestrolis	Methadoni Hydrochloridum
Injectio Digoxini	Methioninum
Injectio Dihydrostreptomycini	Metoponi Hydrochloridum
Injectio Dimercaprolis	Natrii Chloridum
Injectio Emetini Hydrochloridi	Natrii Nitris
Injectio Ergometrini Maleatis	Natrii Para-aminosalicylas
Injectio Ergotamini Tartratis	Natrii Pyrosulfis
Injectio Glucosi	Oleum Hydnocarpi
Injectio Heparini	Oxophenarsini Hydrochloridum
Injectio Histamini Phosphatis	Oxycodoni Hydrochloridum
Injectio Hydromorphoni Hydrochloridi	Pentamidini Dimethylsulfonas
Injectio Hyoscini Hydrobromidi	Phenylhydrargyri Boras
Injectio Lanatosidi C	

Phenylhydrargyri Nitras	Suraminum Natricum
Podophylli Resina	Thyroidea
Procaïni Benzylpenicillinum	Tincturae
Profenamini Hydrochloridum	Tinctura Aconiti
Promethazini Hydrochloridum	Tinctura Belladonnae
Propylthiouracilum	Tinctura Colchici
Solutio Acidi Citratis Glucosi Anti-coagulans	Tinctura Hyoscyami
Solutio Natrii Chloridi Composita (Synonym : Ringer's Solution)	Tinctura Ipecacuanhae
Solutio Natrii Chloridi Isotonica	Tinctura Scillae
Solutio Natrii Citratis Anticoagulans	Tinctura Stramonii
Solutio Natrii Lactatis Composita (Synonym : Ringer's Lactate Solution)	Tinctura Strychni
Streptomycini et Calcii Chloridum	Trichloroethylenum
Streptomycini Hydrochloridum	Trihexyphenidylum
Streptomycini Sulfas	Tripelennamini Hydrochloridum
	Tubocurarine Chloridum
	Tyrothricinum

Appendices

Biological Assay of Chorionic Gonadotrophin	Table of Doses for Children
Biological Assay of Dihydrostreptomycin	Table of Usual and Maximal Doses for Adults
Biological Assay of Serum Gonadotrophin	Test for Pyrogens
Biological Assay of Streptomycin	Test for Sterility of Dihydrostreptomycin
Biological Assay of Tubocurarine Chloride	Test for Sterility of Streptomycin
Determination of Methoxyl	Tests for Freedom from Abnormal Toxicity of Dimercaprol
Limit Test for Iron	

Annex 3**DRAFT PROTOCOL
FOR THE TERMINATION OF THE BRUSSELS AGREEMENTS
FOR THE UNIFICATION OF PHARMACOPOEIAL FORMULAS
FOR POTENT DRUGS**

WHEREAS the publication by the World Health Organization of the *Pharmacopoea Internationalis* has rendered generally obsolete the provisions of the Agreements signed at Brussels on 29 November 1906 and 20 August 1929 for the Unification of Pharmacopoeial Formulas for Potent Drugs,

The States Parties to this Protocol have agreed to the following provisions :

Article 1

The Parties to this Protocol agree that, as between themselves, and as between each State and the World Health Organization, the effects of the following international Agreements shall be terminated :

- (a) Agreement for the Unification of Pharmacopoeial Formulas for Potent Drugs, signed at Brussels on 29 November 1906 ;
- (b) Agreement revising the Agreement respecting the Unification of Pharmacopoeial Formulas for Potent Drugs, signed at Brussels on 20 August 1929.

Article 2

The Parties to this Protocol further agree, as between themselves, and as between each State and the World Health Organization, that any functions previously entrusted, under the provisions of the Agreements listed in Article 1, to the Permanent International Pharmacopoeia Secretariat, shall, after the entry-into-force of this Protocol and in so far as the exercise of such functions continues to be required, be exercised by the World Health Organization.

Article 3

Any State Party to either or both of the Agreements listed in Article 1 which is not a signatory to this Protocol may at any time accept this

Protocol by sending an instrument of acceptance to the Belgian Government who will inform all signatory and other governments which have accepted this Protocol and the World Health Organization of such accession.

Article 4

States may become Parties to this Protocol by :

- (a) signature without reservation as to approval ;
- (b) signature subject to approval followed by acceptance ; or
- (c) acceptance.

Acceptance shall be effected by the deposit of a formal instrument with the Belgian Government.

Article 5

This Protocol shall enter into force when ten States Parties to either or both of the Agreements listed in Article 1 have become Parties to this Protocol, and thereupon certified true copies shall be transmitted by the Belgian Government to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations.

IN FAITH WHEREOF the duly authorized representatives of their respective Governments have signed this Protocol, which is drawn up in the English and French languages, both texts being equally authentic, in a single original which shall be deposited with the Belgian Government. Authentic copies shall be furnished by the Belgian Government to each of the signatory and accepting States and to any other State which, at the time this Protocol is signed, is a Party to either or both of the Agreements listed in Article 1. The Belgian Government shall as soon as possible notify each of the Parties to this Protocol and the World Health Organization of its entry-into-force.

DONE in Geneva this day of 1952.

Annex 4

SUBCOMMITTEE ON NON-PROPRIETARY NAMES

Third Report

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SUBCOMMITTEE ON NON-PROPRIETARY NAMES

Third Session

Geneva, 5 November 1951

Members :

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

Dr. C. H. Hampshire, formerly Secretary, British Pharmacopoeia Commission, General Medical Council Office, London, United Kingdom

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 (*Chairman*)

Dr. L. C. Miller, Director of Revision of the Pharmacopoeia of the United States of America, New York, N.Y., USA (*Vice-Chairman*)

Secretary :

P. Blanc, Chief, Pharmaceutical Section, WHO

The report on the third session of this subcommittee was originally issued in mimeographed form as document WHO/Pharm/176, 14 November 1951.

SUBCOMMITTEE ON NON-PROPRIETARY NAMES

Third Report ¹

The Subcommittee on Non-Proprietary Names held its third session in Geneva on 5 November 1951.

1. Resolutions Adopted by the Executive Board at its Eighth Session

The subcommittee noted the resolution EB8.R42 of the Executive Board ² authorizing the publication of the report on its second session, and the resolution EB8.R41 ³ requesting the Director-General to take, in co-operation with the International Union for the Protection of Industrial Property, the necessary measures for the eventual inclusion, in the International Convention which created the International Union for the Protection of Industrial Property as revised, of suitable provisions for ensuring that international non-proprietary names have, in the general interest, the protection desired in the countries parties to the Convention, and requesting the Director-General to prepare and submit to the World Health Assembly regulations, based on Article 21 (*d*) and (*e*) of the Constitution of WHO, for the legal protection of international non-proprietary names.

2. Protection of International Non-Proprietary Names

The subcommittee noted that the names selected by it at its second session were being forwarded to Member States with a letter from the Director-General requesting that the names should be granted protection with a view to preventing the use of such names for unauthorized purposes

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

1. NOTES the report of the Expert Committee on the International Pharmacopoeia on its ninth session, and the report of the Subcommittee on Non-Proprietary Names on its third session ;
2. THANKS the members of the committee and of the subcommittee for their work, and
3. AUTHORIZES publication of these reports in one volume.
(Resolution EB9.R93, *Off. Rec. World Hlth Org.* 40, 33)

² *Off. Rec. World Hlth Org.* 36, 14

³ *Off. Rec. World Hlth Org.* 36, 13

and in particular to preventing the granting of exclusive proprietary rights in these names to the manufacturers, and that they should be accepted as official international non-proprietary names. In addition, national pharmacopoeial authorities and others interested were informed of the names selected. A number of countries had replied to the letter of the Director-General agreeing to grant protection to the names selected at the first session.

The subcommittee asked Dr. Miller to continue consultation with the American Drug Manufacturers Association with a view to obtaining help from the Combined Trade-Mark Bureau in Washington in order to ascertain whether any of the proposed international non-proprietary names were already registered. By virtue of resolution EB8.R41⁴ arrangements were also being made with the International Union for the Protection of Industrial Property, Berne, to institute a search for names which may have been registered with the International Union by countries parties to the International Convention.

In order to grant protection to these names, besides the request made to the Member States through previous resolutions, the International Union for the Protection of Industrial Property was being asked to take steps to ensure that protection would be granted immediately for a period of six months while a search was being made through the International Union to ensure that the names would not be in conflict with trademarks registered with the International Union. However, this could only apply to names registered internationally through the International Union by States parties to the Convention creating the Union. For names not so registered WHO Member States should be asked to undertake the search and to report within six months whether the names proposed by the subcommittee were in conflict with names previously registered.

The subcommittee noted that a so-called "priority delay" is generally granted in most countries in respect of trademarks and that it would be advantageous to prevent names selected by the subcommittee from being deposited or registered for a period of six months, and made the following recommendation :

The Subcommittee on Non-Proprietary Names of the Expert Committee on the International Pharmacopoeia,

Considering that it is desirable that international non-proprietary names selected by the World Health Organization should not conflict with trademarks deposited or registered throughout the world,

RECOMMENDS that the Director-General, in connexion with his discussions with the International Union for the Protection of Industrial

⁴ *Off. Rec. World Hlth Org.* 36, 13

Property for the protection of non-proprietary names for drugs, propose that arrangements be made for preventing these names being registered as trademarks in any country signatory to the Union Convention signed at Paris on 20 March 1883, revised at Brussels on 14 December 1900, Washington on 2 June 1911, The Hague on 6 November 1925, and London on 2 June 1934, for a period of six months after they have been sent to the Member States, and that a search be instituted during this period, through the International Union for the Protection of Industrial Property and other appropriate means, to ascertain that names selected as international non-proprietary names do not conflict with existing trademarks.

When there is an objection to the adoption of the name decided upon, the proposed name or a closely similar name being already registered as a trademark in a country, a name as similar as possible to the name decided upon and respecting the "General principles for a system of international non-proprietary names"⁵ should be adopted in that country.

The subcommittee suggested that manufacturers seeking international non-proprietary names for new products should approach WHO, if possible through national pharmacopoeia commissions or national health administrations, and stressed the importance of having the names selected, in the first instance, on an international level by WHO. To achieve this the Member States should be asked to forward to WHO names proposed for new drugs before making a final decision.

In view of the need for rapid decision the subcommittee agreed that names received by WHO should be forwarded to members of the subcommittee who would have 15 days to send comments. These would be sent to the Chairman who would decide on the international non-proprietary names to be adopted. In case of difficulty the Chairman would be able to refer the names to the members for further consideration.

Correspondence had also been received concerning difficulties which may arise where more than one non-proprietary name is official in a given country because a non-proprietary name has been adopted there before the notification of an international non-proprietary name. The subcommittee made the following recommendation :

The Subcommittee on Non-Proprietary Names of the Expert Committee on the International Pharmacopoeia,

Considering that until an international non-proprietary name has been adopted by Member States as the only non-proprietary name official in the country for a given drug, there will be in existence in some cases, besides the international non-proprietary name, the non-

⁵ *World Hlth Org. techn. Rep. Ser.* 1951, 43, 29

proprietary name chosen by the pharmacopoeia commission or other similar authority in the country ;

Considering, therefore, that it would be desirable that this source of confusion should be eliminated so that there is only one official non-proprietary name for a drug in a country,

RECOMMENDS

1. that Member States replace such names by the international non-proprietary names selected by the World Health Organization ;
2. that with respect to non-proprietary names for new drugs moving in international commerce the World Health Organization request national pharmacopoeia commissions and other bodies, before taking a decision thereon, to communicate the suggestions for such names under consideration to the World Health Organization for transmission to the Subcommittee on Non-Proprietary Names, without prejudice to the eventual selection of a name by the subcommittee.

3. General Principles to be Followed in Selecting International Non-Proprietary Names

The subcommittee considered a number of comments and proposals on point 8 of the "General principles for a system of international non-proprietary names"⁶ referring to the terminations to be used in devising new names and considered a number of them which might be used in addition to the terminations already established.

4. Graphic Formulae

The subcommittee was of the opinion that, in the lists of international non-proprietary names as published, in addition to chemical names, graphic formulae should be given as defining with precision the chemical compounds concerned. Professor Baggesgaard Rasmussen undertook to provide graphic formulae in all cases where they were required.

5. Date of Next Session

The subcommittee expressed a wish that its next session should take place immediately before or after the next session of the Expert Committee

⁶ *World Hlth Org. techn. Rep. Ser.* 1951, **43**, 29

on the International Pharmacopoeia and that it should last not less than two days.

6. International Non-Proprietary Names

The subcommittee considered lists of names of new therapeutic substances received from national organizations and pharmacopoeia commissions and selected a number of international non-proprietary names (see Appendix 1).

Appendix 1

INTERNATIONAL NON-PROPRIETARY NAMES

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Acidum Gentisicum Gentisic Acid Acide gentisique	5-hydroxysalicylic acid
Acidum Glutamicum Glutamic Acid Acide glutamique	glutamic acid
Aethacridinum Ethacridine Ethacridine	2-ethoxy-6,9-diaminoacridine
Aldesulfonum Natricum Aldesulfone Sodium Aldésulfone sodique	disodium salt of 4,4'-diaminodiphenylsulfone formaldehydesulfoxylic acid
Caramiphenii Chloridum Caramiphenium Chloride Chlorure de caramiphénium	diethylaminoethyl-1-phenylcyclopentane-1-carboxylate hydrochloride
Chlormethinum Chlormethine Chlorméthine	di-(chloroethyl) methylamine
Chloropyrilenii Citras Chloropyrilenium Citrate Citrate de chloropyrilénium	<i>N,N</i> -dimethyl- <i>N'</i> -(2-pyridyl)- <i>N'</i> -(5-chloro-2-thenyl) ethylenediamine citrate
Corticotrophinum Corticotrophin Corticotrophine	adrenocorticotrophic hormone
Doxylaminii Succinas Doxylaminium Succinate Succinate de doxylaminium	2-[α -(2-dimethylaminoethoxy)- α -methylbenzyl]pyridine succinate

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Glucosulfonum Glucosulfone Glucosulfone	<i>p,p'</i> -diaminodiphenylsulfone- <i>N,N'</i> -di-(glucose sodium sulfonate)
Mephenytoinum Mephenytoin Méphénytoïne	3-methyl-5,5-phenylethylhydantoin
Mercaptomerinum Mercaptomerin Mercaptomérine	disodium salt of <i>N</i> -(3-carboxymethylmercapto-mercuri-2-methoxy) propylcamphoric acid
Mercuderamidum Mercuderamide Mercudéramide	hydroxymercuripropanolamide of <i>o</i> -carboxyphenoxycetic acid
Methandriolum Methandriol Méthandriol	17 α -methyl-3 β ,17 β -dihydroxyandrostene-5
Methanthelinii Bromidum Methanthelinium Bromide Bromure de méthanthélinium	β -diethylaminoethyl xanthene-9-carboxylate methylbromide
Methestrolī Dipropionas Methestrol Dipropionate Dipropionate de méthestrol	4,4'-(1,2-diethylethylene)di- <i>o</i> -cresol dipropionate
Methoxyphenaminii Chloridum Methoxyphenaminium Chloride Chlorure de méthoxyphénaminium	2-(<i>o</i> -methoxyphenyl)-isopropylmethylaminium chloride
Methylergometriniī Tartras Methylergometriniū Tartrate Tartrate de méthylergométriniū	D-lysergic acid 2-butanolamide tartrate
Methylphenobarbitalum Methylphenobarbital Méthylphénobarbital	<i>N</i> -methyl-5-ethyl-5-phenyl-barbituric acid
Methylthioninii Chloridum Methylthioninium Chloride Chlorure de méthylthioninium	tetramethylthioninium chloride
Natrii Cyclamas Sodium Cyclamate Cyclamate de sodium	sodium cyclohexylsulfamate
Phenindaminum Phenindamine Phénindamine	2-methyl-9-phenyl-2,3,4,9-tetrahydro-1-pyridine hydrogen tartrate
Phenylephrinum Phenylephrine Phényléphrine	1-methylaminomethyl-(3-hydroxyphenyl) carbinol
Pregnenolonum Pregnenolone Prégnénolone	3-hydroxy-20-keto-pregnene-5

<i>International non-proprietary name</i> (Latin, English, French)	<i>Chemical name or description</i>
Rutosidum Rutoside Rutoside	3-rhamnoglucoside of 5,7,3',4'-tetrahydroxy- flavonol
Thiamazolium Thiamazole Thiamazole	1-methyl-2-mercaptoimidazole
Thonzylaminii Chloridum Thonzylaminium Chloride Chlorure de thonzylaminium	<i>N,N</i> -dimethyl- <i>N'</i> -(<i>p</i> -methoxybenzyl)- <i>N'</i> -(2-pyrimi- dyl) ethylenediamine hydrochloride
Vinbarbitalum Vinbarbital Vinbarbital	sodium derivative of 5-ethyl-5-(1-methyl-1-butenyl) barbituric acid

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