BRITISH PHARMACEUTICAL CODEX 1973

Prepared in the Department of Pharmaceutical Sciences of the Pharmaceutical Society of Great Britain and published by direction of the Society's Council

LONDON
THE PHARMACEUTICAL PRESS
17 BLOOMSBURY SQUARE WC1A 2NN

ANNOUNCEMENT

The Council of the Pharmaceutical Society of Great Britain recommends that the British Pharmaceutical Codex 1973 come into force in the United Kingdom on December 1, 1973. It is open to overseas authorities to fix such a date as is convenient to them.

ISBN 0 85369 084 7

ACKNOWLEDGEMENT

Information from the British Pharmacopoeia is used with permission of the Controller of Her Majesty's Stationery Office.

Made and printed in Great Britain by
William Clowes & Sons, Limited, London, Beccles and Colchester

THE COUNCIL OF THE PHARMACEUTICAL SOCIETY OF GREAT BRITAIN 1972–1973

President: J. P. Kerr, F.P.S.
Vice-President: C. C. B. Stevens, O.B.E., LL.B., F.P.S.
Treasurer: H. Steinman, O.B.E., F.P.S.

A. Aldington, O.B.E., F.P.S.
J. E. Balmford, M.P.S.
J. P. Bannerman, M.P.S.
W. A. Beanland, M.P.S.
Professor A. H. Beckett, D.SC., PH.D., F.P.S., F.R.I.C.
J. C. Bloomfield, F.P.S., J.P.
Mary A. Burr, M.A., F.P.S.
T. K. Cooke, M.B., CH.B.
W. M. Darling, O.B.E., M.P.S.
S. Howard, C.B.E., A.M.C.T.
A. Howells, O.B.E., F.P.S.
K. A. Lees, F.P.S., D.B.A.
Estelle J. M. Leigh, F.P.S.
Enid Lucas-Smith, B.PHARM., F.P.S.
A. G. M. Madge, F.P.S.
J. A. Myers, B.PHARM., F.P.S., LL.B., D.P.A., A.C.I.S.
J. G. Roberts, F.P.S.
A. Roxburgh, F.P.S.
D. E. Sparshott, M.A., M.P.S.
Professor P. Turner, M.D., B.SC., M.R.C.P.
K. W. Youings, F.P.S.

Secretary and Registrar: D. F. Lewis, F.P.S.

CODEX REVISION COMMITTEE

Chairman: H. G. Rolfe, B.SC., F.P.S., F.R.I.C.

J. Allen, F.R.I.C.
Professor A. H. Beckett, D.SC., PH.D., F.P.S., F.R.I.C.
Professor J. W. Fairbairn, D.SC., PH.D., B.SC., F.P.S., F.L.S.
A. G. Fishburn, F.P.S., F.R.I.C., D.P.A.
D. C. Garratt, D.SC., PH.D., F.R.I.C., M.CHEM.A.
J. B. Grosset, O.B.E., F.P.S., D.B.A.
J. W. Hadgraft, F.P.S., F.R.I.C.
J. B. Harman, M.A., M.D., F.R.C.S., F.R.C.P.
K. Holland, F.P.S., D.B.A.
D. Jack, PH.D., B.SC., F.P.S., F.R.I.C.
Professor J. M. Rowson, M.SC., PH.D., D.SC., F.P.S., F.L.S.
D. E. Sparshott, M.A., M.P.S.
T. D. Whittet, PH.D., B.SC., F.P.S., F.R.I.C., D.SC., D.B.A.
Professor A. Wilson, C.B.E., PH.D., M.D., F.P.S., F.R.C.P.

Secretary to the Committee: G. R. Brown, B.PHARM., B.SC., F.P.S.
Director of Revision: S. C. Jolly, B.PHARM., B.SC., M.P.S., F.R.I.C.
General Editor: R. G. Todd, F.P.S.

PREFACE

In 1903 the Council of the Pharmaceutical Society of Great Britain adopted a resolution to produce a book of reference for those engaged in prescribing and dispensing medicines and the first British Pharmaceutical Codex, published in 1907, gave effect to this resolution. Subsequent revisions of the Codex were published in 1911, 1923, 1934, 1949, 1954, 1959, 1963, and 1968. Significant changes were made both in the scope of the book and the method of presenting information in each edition until the fifth. Since 1949, however, the general format of the Codex has remained unchanged until this, the tenth edition, although its scope has continued to extend.

Changes that have been made in the later editions include the introduction of a large number of detailed analytical standards (from 1949), the use of authentic specimens in analytical procedures (from 1963), the reorganisation of the information on drug actions to give due prominence to adverse effects (1968), the introduction of more monographs giving standards for pharmaceutical adjuvants (1968), and the abandonment of the Imperial system of weights and measures in favour of the metric system; this process, which began with the solid dosage forms in the 1963 Codex, continued with the conversion of formulae for liquid preparations in 1968, and is completed in 1973 by changes in the dimensions of surgical dressings.

With each succeeding edition, it has become increasingly difficult to accommodate all the required information within the confines of a volume of convenient size, while retaining the general format so long familiar to users of the Codex. On this occasion, therefore, the opportunity has been taken to reconsider the general lay-out of the text and the Codex is now presented in an entirely redesigned form. Had the old format been retained, the text of this new edition would have occupied some 1850 pages and increased the thickness of the book beyond easily manageable proportions. By modifying the typographical style, increasing the page size, and adopting a double-column format, it has been possible not only to improve the legibility of the text but almost to halve the number of pages required, thus improving the proportions of the book and allowing ample scope for the further expansion of subsequent editions, as necessitated by the continuing progress in the development and use of medicinal products.

At the request of the British Pharmacopoeia Commission, the Council of the Pharmaceutical Society agreed in 1959 that the publication of the Codex should coincide with that of the British Pharmacopoeia, so that new versions of the two books could come into effect on the same dates. This arrangement makes it possible to provide continuing current standards for those drugs and preparations that cease to be the subjects of monographs in the Pharmacopoeia and become the subjects of monographs in the Codex, and *vice versa*. Close co-operation between the British Pharmacopoeia Commission and the Codex Revision Committee has been necessary to provide comparable standards for simultaneous publication, but it is considered that the additional effort involved is justified, as the transition between editions should now be more convenient for users of the two books.

The Codex is also closely linked with the British National Formulary, for which it provides formulae and standards, and arrangements have been made for the new edition of the Formulary to come into effect on the same date as the Pharmacopoeia and the Codex.

This tenth British Pharmaceutical Codex has been prepared by the Codex Revision Committee at the direction of the Council of the Pharmaceutical Society, which acknowledges its great indebtedness to all members of the Committee and its sub-committees for the expert knowledge they have contributed and the valuable time they have so freely given. The membership of the Codex Revision Committee is given on page viii, and that of its sub-committees is set out below.

Actions and Uses Subcommittee

Chairman: T. D. Whittet, PH.D., B.SC., F.P.S., F.R.I.C., D.SC., D.B.A.

G. Bryan, F.P.S.
N. C. Cooper, M.SC., M.P.S.
F. Dudley Hart, M.D., F.R.C.P.
Professor P. C. Elmes, B.M., F.R.C.P.
S. J. Hopkins, F.P.S.
A. P. Launchbury, B.SC., M.P.S.
P. A. Parish, M.D., M.R.C.G.P.
F. Prescott, PH.D., M.SC., M.R.C.P., F.R.I.C.
L. Priest, M.SC., B.PHARM., F.P.S.
Professor H. Schnieden, M.D., M.SC.
Elizabeth J. Stokes, M.B., B.S., F.R.C.P.
Professor P. Turner, M.D., B.SC., M.R.C.P.
Professor D. W. Vere, M.D., M.B., B.S., F.R.C.P.
Professor A. W. Woodruff, M.D., PH.D., F.R.C.P., F.R.C.P.E., D.T.M. and H.

Secretary to the Committee: G. R. Brown

Biological Products Subcommittee

Chairman: D. Jack, PH.D., B.SC., F.P.S., F.R.I.C.

R. D. Andrews, M.B., B.S., B.SC., PH.D.
A. J. Beale, M.D., DIP.BACT., F.R.C.PATH.
A. B. Christie, M.A., M.D., D.P.H., D.C.H.
A. H. Griffith, M.D., D.P.H.
J. A. Holgate, M.B., CH.B., M.SC.
W. d'A. Maycock, M.V.O., M.D., F.R.C.PATH.
F. T. Perkins, B.SC., M.SC., PH.D.
C. H. Smith, M.D., F.R.C.PATH.
A. F. B. Standfast, M.A., SC.D., DIP.BACT.
P. B. Stones, M.B., B.S., F.R.C.PATH.
L. Vallet, M.A.

Secretary to the Committee: G. R. Brown

Formulary Standards Subcommittee A

Chairman: D. C. Garratt, D.SC., PH.D., F.R.I.C., M.CHEM.A.

A. S. Beidas, B.SC., F.R.I.C., M.PH.A.
P. Cleevely, B.SC., F.R.I.C., M.PH.A.
L. E. Coles, B.PHARM., PH.D., F.P.S., F.R.I.C., M.PH.A., M.CHEM.A.
R. E. King, F.R.I.C.
C. A. Macdonald, B.SC., F.R.I.C., M.CHEM.A.
M. J. de Faubert Maunder, B.SC., A.R.I.C.
A. J. Middleton, B.PHARM., M.P.S., F.R.I.C., M.PH.A.
*W. Mitchell, B.SC., PH.D., F.R.I.C.
A. W. C. Peacock, B.PHARM., F.P.S.

Secretary to the Committee: E. S. Greenfield

* Resigned, August 1971

Formulary Standards Subcommittee B

Chairman: D. C. Garratt, D.SC., PH.D., F.R.I.C., M.CHEM.A.

T. M. Blackwood, B.SC.
A. C. Caws, B.SC., A.R.I.C.
A. E. Corker, F.P.S., F.R.I.C.
D. H. Dorken, B.PHARM., M.P.S., F.R.I.C.
M. J. de Faubert Maunder, B.SC., A.R.I.C.
C. Radford, F.P.S.
R. Sinar, B.PHARM., B.SC., F.P.S., F.R.I.C.
D. O. Singleton, B.SC., F.R.I.C.
W. H. Stephenson, F.P.S., F.R.I.C., D.B.A., M.PH.A., M.CHEM.A.
W. R. Thompson, M.SC., F.R.I.C., M.CHEM.A.

Secretary to the Committee: E. S. Greenfield

Ligatures and Sutures Subcommittee

Chairman: K. R. Capper, PH.D., B.PHARM., F.P.S., D.I.C., F.R.I.C.

J. S. Amor, B.SC.
C. Buckler
R. B. Christie, M.P.S.
J. Owen Dawson, B.SC., F.P.S.
Professor H. Ellis, D.M., M.CH., F.R.C.S.
J. A. Holgate, M.B., CH.B., M.SC.
H. V. Rosewarn
D. J. Smith, PH.D., B.SC.
D. G. Thompson
C. C. Yates, A.R.I.C.

Secretary to the Committee: K. B. K. Davis

Pharmaceutical Chemistry Subcommittee

Chairman: Professor A. H. Beckett, D.SC., PH.D., F.P.S., F.R.I.C.

A. J. Badby, B.SC., F.R.I.C.
A. C. Caws, B.SC., A.R.I.C.
G. Drewery, B.SC., F.R.I.C., M.CHEM.A.
A. Holbrook, F.R.I.C., M.CHEM.A.
G. F. Phillips, M.SC., F.R.I.C.
H. T. Searle, M.A., B.SC.
J. E. Shinner, F.P.S.
W. H. Stephenson, F.P.S., F.R.I.C., D.B.A., M.PH.A., M.CHEM.A.
W. R. Thompson, M.SC., F.R.I.C., M.CHEM.A.

Secretary to the Committee: E. S. Greenfield

Pharmacognosy Subcommittee A

Chairman: Professor J. W. Fairbairn, D.SC., PH.D., B.SC., F.P.S., F.L.S.

W. E. Court, M.PHARM., PH.D., F.P.S., F.L.S.
D. F. Cutler, PH.D., B.SC., F.L.S., D.I.C.
W. C. Evans, B.PHARM., PH.D., D.SC., F.P.S.
F. Fish, B.PHARM., PH.D., F.P.S.
Betty P. Jackson, B.PHARM., PH.D., B.SC., F.P.S., F.L.S.
G. B. Pickering, M.A., B.SC., D.PHIL., A.R.I.C.
M. H. Ransom, B.PHARM., M.P.S.
Professor E. J. Shellard, B.PHARM., PH.D., F.P.S., F.R.I.C., F.L.S.
G. R. A. Short, F.P.S., F.L.S.
A. A. Williams
A. J. Woodgate, B.SC., A.R.I.C.

Secretary to the Committee: K. B. K. Davis

Pharmacognosy Subcommittee C

Chairman: D. C. Garratt, D.SC., PH.D., F.R.I.C., M.CHEM.A.

D. Holness, B.A.
A. M. Humphrey, B.SC., A.R.C.S.
P. A. Linley, PH.D., B.PHARM., M.P.S.
C. A. Macdonald, B.SC., F.R.I.C., M.CHEM.A.
*W. Mitchell, B.SC., PH.D., F.R.I.C.
N. Nix, B.SC., F.R.I.C.
R. A. Rabnott
M. H. Ransom, B.PHARM., M.P.S.
Professor E. J. Shellard, B.PHARM., PH.D., F.P.S., F.R.I.C., F.L.S.

Secretary to the Committee: E. S. Greenfield

* Resigned, August 1971

Pharmacy Subcommittee A

Chairman: J. W. Hadgraft, F.P.S., F.R.I.C.

C. F. Abbott, B.PHARM., B.SC., F.P.S., F.R.I.C.
C. W. Barrett; M.PHARM., M.P.S.
Professor J. E. Carless, B.PHARM., M.SC., PH.D., F.P.S.
C. L. J. Coles, B.PHARM., F.P.S.
A. E. Davis, B.PHARM., F.P.S.
D. N. Gore, F.P.S., F.R.I.C.
W. H. Howarth, M.P.S.
Christobel E. Mozley-Stark, M.B.E., F.P.S.
A. W. Newberry, F.P.S.
J. R. Phillips, F.P.S.
G. Smith, PH.D., B.SC., F.P.S.
F. H. Tresadern

Secretary to the Committee: K. B. K. Davis

Formulation Panel. G. Smith (*Chairman*), A. E. Davis, A. W. Newberry, and F. H. Tresadern. *Secretary:* W. Lund

Dispensing Panel. J. R. Phillips (*Chairman*), W. H. Howarth, J. G. Iles, B.SC., M.P.S., A. King, F.P.S., and C. McArdle, F.P.S. *Secretary:* K. B. K. Davis

Pharmacy Subcommittee B

Chairman: J. W. Hadgraft, F.P.S., F.R.I.C.

A. W. Baker, F.P.S., D.B.A.
H. S. Bean, PH.D., B.PHARM., F.P.S.
W. R. L. Brown, B.PHARM., PH.D., F.P.S.
J. P. Curtis, F.P.S.
A. E. Davis, B.PHARM., F.P.S.
D. J. Drain, B.A., F.R.I.C.
J. Flint, F.P.S.
Professor D. A. Norton, B.SC., F.P.S., D.B.A., A.C.T., F.I.BIOL.
W. J. W. Price, F.P.S.
G. Smith, PH.D., B.SC., F.P.S.

Secretary to the Committee: K. B. K. Davis

Surgical Dressings Subcommittee

Chairman: L. B. Tansley, M.C., M.A., M.SC., F.R.I.C.

F. Carus
R. Crabtree
J. Flint, F.P.S.
D. C. Harrod, B.SC., F.P.S., F.L.S.
H. A. Hunt, B.SC.
E. Jones, B.SC., F.R.I.C.
R. Lant, B.SC., A.R.I.C.
K. Lunn, B.SC.
R. Maxwell-Savage, PH.D., M.A., F.R.I.C.
B. W. Mitchell, B.A., B.SC., F.R.I.C.
Christobel E. Mozley-Stark, M.B.E., F.P.S.
J. A. Myers, B.PHARM., F.P.S., LL.B., D.P.A., A.C.I.S.
P. J. Perry
R. Robinson, B.SC.
J. T. Scales, F.R.C.S., L.R.C.P.
T. D. Turner, M.PHARM., M.P.S., F.L.S.

Secretary to the Committee: E. S. Greenfield

Panel on Performance of Surgical Dressings. T. D. Turner (*Chairman*), K. J. Harkiss, M.SC., PH.D., M.P.S., K. Lunn, B. W. Mitchell, P. J. Perry, and J. T. Scales.

Panel on Sterility Testing of Surgical Dressings. P. E. Harbord, A.I.M.L.T., E. Jones, A. Keale, B.SC., A. F. Lott, B.SC., R. Maxwell-Savage, and G. Sykes, M.SC., F.R.I.C.

K. B. K. Davis, M.P.S., and E. S. Greenfield, members of the staff of the Department of Pharmaceutical Sciences, have acted as secretaries to the committees and assisted with editorial work. In the laboratories of the Department of Pharmaceutical Sciences, formulation problems were investigated by W. Lund, F.P.S., assisted by A. A.

Chalmers, B.SC., M.P.S., Mary Neil, M.P.S., Veronica Russell, B.SC., M.P.S., I. E. Williams, B.PHARM., M.P.S., and Elma J. W. Young, B.SC., A.R.C.S.T., M.P.S., while analytical problems were investigated by J. D. Edmond, B.SC., A.R.I.C., assisted by D. Glencorse and Margaret Scott, B.SC.

Dorothy E. Aimes, Susan Cross, B.PHARM., M.P.S., H. C. Happold, M.P.S., D. A. Kennedy, Wendy Oliver, B.PHARM., M.P.S., and Gwyneth Wass also assisted in the preparation of the text and in reading the proofs.

The Codex Revision Committee gratefully acknowledges the invaluable assistance and advice it has received from government departments, professional institutions, and other organisations, including the Association of the British Pharmaceutical Industry, the British Standards Institution, the Commissioners of Customs and Excise, the Department of Health and Social Security, the Faculty of Ophthalmologists, the Home Office (drugs branch), the Laboratory of the Government Chemist, the Medical Research Council, the National Pharmaceutical Union, the Royal Botanic Gardens, Kew, and the Society for Analytical Chemistry.

Valuable advice has also been received from various overseas authorities, particularly the Department of Health, Australia, the Department of Health and Welfare, Canada, and the Directorate General of Health Services, India, and this advice has been of great assistance to the committee in ensuring that the statements in the Codex are acceptable in many countries.

Numerous experts have provided information and advice on specific points, especially the following: A. G. Allnutt, G. Ansell, E. H. Fagg, R. Goulding, J. P. Griffin, S. F. Hall, C. A. Johnson, G. R. Kitteringham, K. W. Lovel, D. E. Lovett, D. Mansel-Jones, J. P. Nicholson, S. Powlson, G. A. Rose, A. J. P. Shearlaw, A. D. Thornton-Jones, and A. Wade. The continued co-operation of the British Pharmacopoeia Commission and the help of numerous pharmaceutical manufacturers and of pharmacists in hospital and general practice are also gratefully acknowledged.

The Codex Revision Committee has also co-operated with the World Health Organisation in the preparation and revision of relevant standards of the International Pharmacopoeia and has also advised the British Delegation to the European Pharmacopoeia Commission on various monographs.

INTRODUCTION

The British Pharmaceutical Codex fulfils two important functions, namely, to give information on drugs, other pharmaceutical substances, and formulated products, and to provide standards for a range of substances and materials that are not included in the British Pharmacopoeia. It provides authoritative information on the actions and uses of drugs and on their pharmaceutical properties. As new monographs are added to the Codex, it is necessary to omit monographs on older and less frequently used drugs and pharmaceutical adjuvants in order to keep the size of the book within reasonable limits, but the policy, introduced in the last edition, of including any substance which is in sufficiently wide use for a published standard to be desirable has been continued in this edition.

The work of revision has been influenced by the coming into effect in the United Kingdom of various sections of the Medicines Act 1968 which has resulted in the manufacture of medicinal products being controlled by a system of licensing. By virtue of section 65 of the Act the British Pharmaceutical Codex standards are recognised for relevant medicinal products, and the standards of the European Pharmacopoeia and of the British Pharmacopoeia are applicable where stated in the monographs.

The most important aspects of this revision are discussed briefly in the following pages.

Part 1. Drugs and Pharmaceutical Adjuvants

Monographs have been added on a variety of substances including aminobenzoic acid (which has sun-screening properties), calcium, magnesium, and potassium acetates (used in the preparation of haemodialysis solutions), chlorpromazine (for the preparation of suppositories), coconut oil (used as an ointment basis), and hydrocortisone sodium phosphate (used in the preparation of the injection). Other additions include antibiotics, β-adrenergic blocking agents, local anaesthetics, cytotoxic agents, and radiopharmaceuticals, including the important diagnostic material, sodium pertechnetate (^{99m}Tc). Monographs are included on all the substances of the British Pharmacopoeia 1973 with the exception of Alprenolol Hydrochloride. The Committee considered that at the time of preparation of the text there was not enough experience of the use of this substance to enable a sufficiently authoritative monograph to be prepared.

In this revision, particular attention has been paid to extending the information on the pharmaceutical properties of Codex substances and preparations and on their stability, incompatibility, storage, and sterilisation.

Earlier editions of the Codex were accompanied by a pamphlet containing names that were not recognised as synonyms for the Codex substances but that were sometimes applied to these substances or their preparations. For convenience in reference, these names have now been appended to the monographs and included in the index.

They comprise both proprietary and non-proprietary names and they have been placed, after the subheading "OTHER NAMES", at the foot of the monographs to which they refer so as to distinguish them from the synonyms at the head of the monographs, which have the same status as the main titles. The synonyms have been revised to include the Latin titles used in volumes I and II of the European Pharmacopoeia; other Latin titles, formerly widely used, have been omitted except in certain instances where they differ significantly from the English titles.

Part 2. Immunological Products and Related Preparations

The information on these products has been revised and considerable rearrangement of the monographs has been necessary as a result of the coming into effect in the United Kingdom of the standards of the European Pharmacopoeia. The recommendations on the immunisation of children and of travellers have been amended to conform to current practice, and, where appropriate, to the latest recommendations of the Department of Health and Social Security.

Part 3. Preparations of Human Blood

The information in this section has been revised to conform to modern practice; in particular, precautions to minimise the risk of transmitting serum hepatitis have been strengthened as a result of the development of tests to detect Australia (hepatitis-associated) antigen.

Part 4. Surgical Ligatures and Sutures

In this edition the former B.P.C. gauge numbers have been omitted and only the metric size designations, first introduced in the 1968 Codex, have been retained. These metric size designations and the standards, except those for stainless steel sutures, have been modified to conform to the requirements of the European Pharmacopoeia.

Part 5. Surgical Dressings

Many changes in points of detail have been made in the monographs. A test for colour fastness has been introduced and the sterility test has been completely revised.

Part 6. Formulary

Close co-operation with the Joint Formulary Committee, responsible for the revision of the British National Formulary, has been continued and further monographs have been added to this edition to provide standards for and other information on preparations included in the British National Formulary 1973; examples of such preparations are Betamethasone Valerate Scalp Application, Clioquinol Cream, Betamethasone Eye-drops, Hydrocortisone Sodium Phosphate Injection, and Betamethasone Valerate Lotion. Development work was undertaken by members of the pharmacy subcommittees and the Society's laboratories to establish the formula for Isoniazid Elixir; patient acceptability tests were carried out at several hospitals.

The introduction of a monograph on Diamorphine and Cocaine Elixir provides a

standard formula for the preparation used for the relief of pain in terminal carcinoma and the last stages of other painful and fatal illnesses; the formula is capable of adjustment to the needs of the patient and if the prescriber so indicates the strength can be varied and morphine can be used instead of diamorphine. This monograph also provides for the inclusion of chlorpromazine in the elixir.

The formula for Aminobenzoic Acid Lotion is based on the reports of M. A. Pathak, T. B. Fitzpatrick, and E. Frenk, *New Engl. J. Med.*, 1969, **280**, 1459 and I. Willis and A. M. Kligman, *Archs Derm.*, 1970, **102**, 405 who have shown that it is an effective preparation for the protection of the skin of light-sensitive persons. The formula was selected after investigation of published information by the Society's laboratories and members of the subcommittees.

Investigations in the Society's laboratories have resulted in the addition to the monograph on idoxuridine of information on the preparation of solutions for injection. Such solutions are occasionally required for the treatment of life-threatening systemic viral infections, and formulation must take into consideration that the breakdown products are toxic and that idoxuridine has its optimum stability and lowest solubility at the same pH. The method given is based on the practical examination of published methods and reduces idoxuridine breakdown to an acceptable level. The formulation of eye-drops and an eye ointment of idoxuridine is under investigation with a view to the publication of monographs at a later date.

Work on the formulation of eye-drops has been continued and the range of formulae has been extended. The requirement that multiple-dose containers of eye-drops issued for domiciliary treatment should bear a statement that the drops should not be used for more than one month after first opening the container has been abandoned, following representations from the Faculty of Ophthalmologists that some patients continued to misinterpret such directions and discontinued the treatment, a practice that is more likely to harm them than the possible risk of infection due to using old eye-drops. However, the volume limit of 10 ml per container has been retained and thus in most cases there will be insufficient solution supplied for the contents to be used for a prolonged period.

A working party appointed by the Central Health Services Council is reviewing recommendations for the use of eye-drops in hospitals. The statements in this edition of the Codex are believed to be in accord with the views of the working party but may need to be reviewed when the working party has published its report.

In revising the formulae of mixtures and similar preparations account has been taken of the findings of the Public Health Laboratory Service Working Party (*Pharm. J.* 1971, **207**, 96), which showed that alkaline mixtures are especially liable to microbial growth. Mixtures are now required to be prepared with water of low bacterial content, and most formulae include a preservative such as chloroform. Peppermint oil is added, if required, in the form of a concentrated emulsion. Most of the mixtures contain 0·25 per cent v/v of chloroform, incorporated in the form of double-strength chloroform water. Water of low bacterial count is also required for other aqueous preparations in which bacterial growth is liable to occur, and suitable water is defined in the introduction to the Formulary Section (page 642).

In this edition general standards for pessaries and suppositories have been added. The policy of adding tests for the presence of active ingredients of medicinal products, begun in the last edition, has been continued.

Appendixes

The information provided in appendixes has been greatly extended. Details of ultraviolet absorption spectra required for identification purposes have been collected together in an appendix instead of being given in the monographs. Other appendixes describe general methods of ascending paper chromatography, the determination of distillation range and boiling-point, and the determination of water.

For the determination of alcohol in preparations described in the Codex the traditional distillation method is still used; this method is considered to be the most convenient when dealing with isolated samples. The gas-liquid chromatographic method may be advantageous when dealing with a large series of samples, and analysts may use such a method provided they are satisfied that the method they adopt gives equivalent results.

The appendix on thin-layer chromatography has been expanded and includes a large number of individual identification tests and tests for specific impurities in substances and medicinal products. Many of these tests have been specially developed in the laboratories of the Pharmaceutical Society at the instigation of the analytical subcommittees. In addition, general methods for the identification of certain steroids in preparations and for the identification of phenothiazine derivatives have been included. The scheme for the identification of alkaloids in medicinal products, originally included in the last edition of the Codex, has been reorganised to avoid the need for extensive cross referencing.

The quantitative tests for arsenic and lead in Appendixes 6 and 7 have been entirely rearranged to improve legibility and ease of reference.

In the appendix on powders and suspensions (page 911), the designation of sieve sizes has been amended to conform to British Standard 410:1969.

Appendix 28 (page 917) is an interpretation of the test for sterility of the European Pharmacopoeia designed to make the test applicable to surgical dressings and non-absorbable sutures.

European Pharmacopoeia

The Codex Revision Committee has co-operated with other authorities in the preparation of a European Pharmacopoeia published under a convention signed by the governments of Belgium, France, West Germany, Italy, Luxembourg, the Netherlands, Switzerland, and the United Kingdom. From the date of coming into effect of any volume of the European Pharmacopoeia, the standards in its monographs on any article become the standards in the United Kingdom for that article when used in the practice of medicine, surgery, or midwifery.

For the convenience of users of the Codex, those monographs in the 1973 Codex on substances for which a standard was formerly set by the Codex and is now (1973) set by the European Pharmacopoeia have been brought into agreement with the require-

ments of the European Pharmacopoeia. In order that these monographs shall conform to the style of the other Codex monographs it has been necessary to reword to some extent the pharmacopoeial standards and in certain cases to place an interpretation upon those pharmacopoeial statements which are ambiguous. Every care has been taken to ensure that the wording in the Codex monographs does not change the intentions of the European Pharmacopoeia Commission, but it must be emphasised that the requirements of that book are the legal standards in the United Kingdom and that in any case of dispute it is necessary to refer to the original text.

There has been insufficient time during the current revision to treat in the same way those monographs in the 1973 Codex on substances for which a standard was formerly set by the British Pharmacopoeia and is now set by the European Pharmacopoeia. For those monographs there is now a simple statement under the side-heading "Standard" to the effect that the substance must comply with the requirements of the European Pharmacopoeia in the same way that reference is made in monographs on substances for which the British Pharmacopoeia provides the standard. This has resulted in a few anomalies, which will be noted if, for example, the Codex monographs on Senna Leaf and Senna Fruit and on Sterilised Surgical Catgut and Non-absorbable Surgical Sutures are compared.

ADDITIONS

The following monographs of the British Pharmaceutical Codex 1973 were not included in the British Pharmaceutical Codex 1968 as amended by the Supplement 1971.

Part 1. Drugs and Pharmaceutical Adjuvants

Aluminium Phosphate Gel
Dried Aluminium Phosphate Gel
Aminobenzoic Acid
Calcium Acetate
Capreomycin Sulphate
Carbenoxolone Sodium
Cardamom Oil
Cephalexin
Chlorpromazine
Clomiphene Citrate
Coconut Oil
Danthron
Deslanoside
Dextran 70 Injection
Dextrose Monohydrate for Parenteral Use
Fenfluramine Hydrochloride
Framycetin Sulphate
Fusidic Acid
Hydrocortisone Sodium Phosphate
Isoprenaline Hydrochloride
Light Kaolin (Natural)
Lanatoside C
Levodopa
Macrisalb (^{131}I) Injection
Macrogol 1540
Magnesium Acetate
Meglumine Diatrizoate Injection
Melarsoprol Injection
Fractionated Palm Kernel Oil
Potassium Acetate
Practolol
Prilocaine Hydrochloride
Propanidid
Propicillin Potassium
Salbutamol Sulphate
Secbutobarbitone
L-Selenomethionine (^{75}Se) Injection
Sodium Methyl Hydroxybenzoate
Sodium Pertechnetate (^{99m}Tc) Injection
Sodium Propyl Hydroxybenzoate
Tetracosactrin Acetate
Tropicamide
Vincristine Sulphate
Xenon (^{133}Xe) Injection
Xylose

ADDITIONS (*continued*)

Part 2. Immunological Products and Related Preparations

Adsorbed Diphtheria Vaccine
Adsorbed Diphtheria and Tetanus Vaccine
Adsorbed Diphtheria, Tetanus, and Pertussis Vaccine
Eltor Vaccine
Rubella Vaccine (Live Attenuated)
Dried Smallpox Vaccine
Adsorbed Tetanus Vaccine
Typhoid Vaccine
Typhoid and Tetanus Vaccine

Part 3. Preparations of Human Blood

Human Albumin
Dried Human Albumin
Dried Human Antihaemophilic Fraction
Dried Human Fibrinogen for Isotopic Labelling
Human Tetanus Immunoglobulin
Human Vaccinia Immunoglobulin

Part 4. Surgical Ligatures and Sutures

Polyamide 6 Suture
Sterile Polyamide 6 Suture
Polyamide 6/6 Suture
Sterile Polyamide 6/6 Suture

Part 5. Surgical Dressings

Cotton Conforming Bandage
Absorbent Ribbon Gauze, X-ray-detectable
Absorbent Viscose Wadding

Part 6. Formulary

Betamethasone Valerate Scalp Application
*Paromomycin Capsules
Clioquinol Cream
Ipecacuanha Emetic Draught, Paediatric
*Cascara Elixir
Chlorpromazine Elixir
Diamorphine and Cocaine Elixir
Isoniazid Elixir
Propicillin Elixir
Peppermint Emulsion, Concentrated
*Hyoscyamus Dry Extract
*Hyoscyamus Liquid Extract
Betamethasone Eye-drops
Chloramphenicol Sodium Succinate Injection
Hydrocortisone Sodium Phosphate Injection
Procyclidine Injection
*Suramin Injection
Aminobenzoic Acid Lotion
Betamethasone Valerate Lotion
Cephalexin Mixture
Co-trimoxazole Mixture
Fusidic Acid Mixture
Indomethacin Mixture
Betamethasone Valerate with Chlortetracycline Ointment
Gentamicin Ointment
Hydrocortisone and Clioquinol Ointment
Nystatin Ointment
*Paraffin Ointment
*Kaolin Poultice
*Calcium Hydroxide Solution
Chlorhexidine Solution, Dilute
*Morphine Hydrochloride Solution
Chlorpromazine Suppositories
*Tolu Syrup
*Carbromal Tablets
*Gentian Tincture, Compound

In addition to the above individual monographs there are also additions in the form of short introductions to various groups of products included in the Formulary.

* A monograph for a preparation of similar or identical composition was included in the British Pharmacopoeia 1968.

ADDITIONS (*continued*)

The following monographs were added to the British Pharmaceutical Codex 1968 by means of amendments and of the Supplement 1971.

Part 1. Drugs and Pharmaceutical Adjuvants

Allopurinol
Aminocaproic Acid
Amitriptyline Embonate
Amphotericin
Azathioprine
Beclomethasone Dipropionate
Bethanidine Sulphate
Bupivacaine Hydrochloride
Carbamazepine
Carbenicillin Sodium
Cephalothin Sodium
Chlormerodrin (^{197}Hg) Injection
Clofibrate
Desferrioxamine Mesylate
Diazepam
Diphenoxylate Hydrochloride
Doxycycline Hydrochloride
Dydrogesterone
Ecothiopate Iodide
Ethambutol Hydrochloride
Ethynodiol Diacetate
Fluocortolone Hexanoate
Fluocortolone Pivalate
Fluphenazine Hydrochloride
Gentamicin Sulphate
Haloperidol
Hydroxyprogesterone Hexanoate
Idoxuridine
Indomethacin
Inulin
Iodinated (^{125}I) Human Albumin Injection
Lincomycin Hydrocholoride
Lithium Carbonate
Mefenamic Acid
Megestrol Acetate
Melphalan
Metformin Hydrochloride
Methacycline Hydrochloride
Methaqualone
Methotrexate
Metyrapone
Mexenone
Nitrazepam
Pentagastrin
Phenformin Hydrochloride
Prothionamide
Protriptyline Hydrochloride
Riboflavine Phosphate (Sodium Salt)
Salbutamol
Selenium Sulphide
Sodium Cromoglycate
Sodium Iodide (^{125}I) Solution
Sorbitol
Sulphamethoxazole
Thiabendazole
Thiacetazone
Thiotepa
Tolnaftate
Trimethoprim
Trimipramine Maleate
Vinblastine Sulphate

Part 6. Formulary

Aerosol Inhalations
Ergotamine Aerosol Inhalation
Isoprenaline Aerosol Inhalation
Isoprenaline Aerosol Inhalation, Strong
Orciprenaline Aerosol Inhalation
Salbutamol Aerosol Inhalation
Selenium Sulphide Scalp Application
Mexenone Cream
Cloxacillin Elixir
Digoxin Elixir, Paediatric
Orciprenaline Elixir
Phosphates Enema
Prednisolone Enema
Physostigmine and Pilocarpine Eye-drops
Hydrocortisone and Neomycin Eye Ointment
Lignocaine Gel
Sodium Aminosalicylate and Isoniazid Granules
Corticotrophin Carboxymethylcellulose Injection
Dextromoramide Injection
Phenytoin Injection
Codeine Linctus, Diabetic
Zinc Sulphide Lotion