BRITISH PHARMACEUTICAL CODEX

1968

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

馆藏专用章
0008 4130
1973年2月23日上午

LONDON
THE PHARMACEUTICAL PRESS
17 BLOOMSBURY SQUARE WC1

First Impression September 1968

Copyright © 1968 by the Pharmaceutical Society of Great Britain

MADE AND PRINTED BY OFFSET IN GREAT BRITAIN BY
WILLIAM CLOWES AND SONS, LIMITED, LONDON AND BECCLES

THE COUNCIL OF THE PHARMACEUTICAL SOCIETY OF GREAT BRITAIN 1967–1968

President: A. Aldington, F.P.S., A.R.P.S.
Vice-President: A. Howells, F.P.S.
Treasurer: H. Steinman, 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.
E. A. Brocklehurst, F.P.S., J.P.
Mary A. Burr, M.A., F.P.S.
W. M. Darling, M.P.S.
J. B. Grosset, F.P.S., D.B.A.
J. P. Kerr, M.P.S.
W. Lane-Petter, M.A., M.B., B.Chir., F.I.Biol.
J. Levy, M.P.S.
D. H. Maddock, B.Pharm., M.P.S.
A. G. M. Madge, M.P.S.
J. A. Myers, B.Pharm., F.P.S., LL.B., D.P.A., F.C.C.S.
T. Reid, F.P.S., F.H.-W.C.
D. N. Sharpe, M.P.S.
D. E. Sparshott, M.A., M.P.S.
C. C. B. Stevens, LL.B., F.P.S.
M. Weatherall, M.A., D.M., D.Sc.
S. R. F. Whittaker, D.L., M.A., M.D., F.R.C.P.

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

ACKNOWLEDGMENT

The Council of the Pharmaceutical Society of Great Britain acknowledges the assistance received from the British Pharmacopoeia Commission, and the permission granted by the General Medical Council to include in the British Pharmaceutical Codex information relating to substances and preparations contained in the British Pharmacopoeia.

此为试读，需要完整PDF请访问：www.ertongbook.com

CODEX REVISION COMMITTEE

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

Professor A. H. Beckett, D.Sc., Ph.D., F.P.S., F.R.I.C.
H. Treves Brown, B.Sc., F.P.S.
K. R. Capper, Ph.D., B.Pharm., F.P.S., D.I.C., F.R.I.C.
H. Davis, C.B.E., Ph.D., B.Sc., F.P.S., F.R.I.C.
G. Deas Drummond, B.Sc., F.P.S.
Professor J. W. Fairbairn, D.Sc., Ph.D., B.Sc., F.P.S., F.R.I.C., F.L.S.
A. G. Fishburn, F.P.S., D.P.A., F.R.I.C.
D. C. Garratt, D.Sc., Ph.D., F.R.I.C.
J. W. Hadgraft, F.P.S., F.R.I.C.
K. Holland, M.P.S., D.B.A.
D. Jack, Ph.D., B.Sc., F.P.S., F.R.I.C.
W. C. Johnson, M.B.E., F.R.I.C.
T. Reid, F.P.S., F.H.-W.C.
Professor J. M. Rowson, Ph.D., M.Sc., F.P.S., F.L.S.
Professor J. B. Stenlake, D.Sc., Ph.D., F.P.S., F.R.I.C., F.R.S.E.
Professor A. Wilson, Ph.D., M.D., F.P.S., F.R.F.P.S.

Secretary to the Committee: G. R. Brown, B.Pharm., B.Sc., F.P.S.

Editor: S. C. Jolly, B.Pharm., B.Sc., M.P.S., F.R.I.C.

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. Subsequently, revisions of the Codex were published in 1911, 1923, 1934, 1949, 1954, 1959, and 1963. Significant changes were made in both the scope of the book and the method of presenting information in each Codex until the fifth. Since 1949, however, the general format of the book has remained unchanged. The scope of the present work has been increased somewhat, owing to the need to provide standards for a wider range of 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 subject of a monograph in the Pharmacopoeia and become the subject of a monograph in the Codex, and *vice versa*. Close co-operation between the Commission and the 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 books. It is expected that a new issue of the British National Formulary will come into effect on the same date as the Pharmacopoeia and the Codex.

This ninth 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 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 the sub-committees is as follows:

Action and Uses Subcommittee

Chairman: H. Treves Brown, B.Sc., F.P.S.

G. R. Boyes, B.Sc., L.M.S.S.A., F.P.S., F.R.I.C.

*Professor G. Brownlee, D.Sc., Ph.D., F.P.S.

G. Bryan, F.P.S.

Professor G. A. H. Buttle, O.B.E., M.A., M.R.C.S., L.R.C.P.

L. G. Goodwin, M.B., B.S., B.Pharm., B.Sc., F.P.S.

J. H. Harrison, M.R.C.S., L.R.C.P., F.P.S.

F. Dudley Hart, M.D., F.R.C.P.

A. Herxheimer, M.B., B.S.

Professor A. D. Macdonald, M.A., M.D., M.Sc.

F. Prescott, Ph.D., M.Sc., M.R.C.P., F.R.I.C.

L. Priest, M.Sc., B.Pharm., F.P.S.

G. F. Somers, Ph.D., D.Sc., F.P.S.

T. D. Whittet, Ph.D., B.Sc., F.P.S., F.R.I.C., D.B.A.

Secretary to the Committee: G. R. Brown

* Resigned, February 1966

Biological Products Subcommittee

Chairman: D. Jack, B.Sc., Ph.D., F.P.S., F.R.I.C.

A. J. Beale, M.D., Dip.Bact., M.C.Path.

A. B. Christie, M.A., M.D., D.P.H., D.C.H.

Professor D. G. Evans, D.Sc., Ph.D., F.C.Path., F.R.S.

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., M.R.C.S., L.R.C.P., F.C.Path.

F. T. Perkins, B.Sc., M.Sc., Ph.D.

A. F. B. Standfast, M.A., Sc.D., Dip.Bact.

P. B. Stones, M.B., B.S., F.C.Path.

Secretary to the Committee: G. R. Brown

Formulary Standards Subcommittee A

Chairman: D. C. Garratt, D.Sc., Ph.D., F.R.I.C.

A. S. Beidas, B.Sc., M.Ph.A., F.R.I.C.

*P. J. Cooper, B.Sc., F.R.I.C.

G. J. W. Ferrey, B.Sc., F.R.I.C.

R. W. Gillham, F.P.S., D.P.A., F.R.I.C.

Wm. Mitchell, B.Sc., Ph.D.

R. Sinar, B.Pharm., B.Sc., F.P.S., M.Ph.A., F.R.I.C.

E. W. Summers, B.Sc., L.R.I.C.

Secretary to the Committee: E. S. Greenfield

* Resigned, April 1967

Formulary Standards Subcommittee B

Chairman: D. C. Garratt, D.Sc., Ph.D., F.R.I.C.

D. C. M. Adamson, F.R.I.C.

J. Allen, F.R.I.C.

L. E. Coles, Ph.D., F.P.S, M.Ph.A., F.R.I.C.

*P. J. Cooper, B.Sc., F.R.I.C.

A. E. Corker, F.P.S., F.R.I.C.

G. E. Foster, Ph.D., B.Sc., F.R.I.C.

E. F. Hersant, B.Pharm., Ph.D., F.P.S., F.R.I.C.

W. H. Stephenson, F.P.S., M.Ph.A., F.R.I.C.

S. G. E. Stevens, B.Sc., F.R.I.C.

Secretary to the Committee: E. S. Greenfield

* Resigned, April 1967

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

C. Buckler

R. B. Christie

J. Owen Dawson, B.Sc., F.P.S.

H. Cormack

J. A. Holgate, M.B., Ch.B., M.Sc.

*L. J. Kings, M.P.S.

E. Lloyd, B.Sc.

D. G. Thompson

B. A. Wills, B.Pharm., Ph.D., M.P.S. A.R.I.C.

C. C. Yates, A.R.I.C.

Secretary to the Committee: Pamela M. North

* Resigned, October 1966

Pharmaceutical Chemistry Subcommittee A

Chairman: Professor J. B. Stenlake, D.Sc., Ph.D., F.P.S., F.R.I.C., F.R.S.E.

J. Allen, F.R.I.C.
D. C. M. Adamson, F.R.I.C.
A. J. Badby, B.Sc., F.R.I.C.
G. E. Foster, Ph.D., B.Sc, F.R.I.C.
*E. G. Kellett, M.A., D.Phil., B.Sc.
G. F. Phillips, M.Sc., F.R.I.C.
Professor F. A. Robinson, D.Sc., M.Sc.(Tech.), LL.B., F.R.I.C.
J. E. Shinner, F.P.S.
W. H. Stephenson, F.P.S., M.Ph.A., F.R.I.C.

Secretary to the Committee: E. S. Greenfield

* Resigned, October 1966

Pharmaceutical Chemistry Subcommittee B

Chairman: W. C. Johnson, M.B.E., F.R.I.C.

A. S. Beidas, B.Sc., M.Ph.A., F.R.I.C.
J. S. Coleman, B.Pharm., B.Sc., F.P.S., A.R.I.C.
L. W. Cumming, F.R.I.C.
E. Mather, F.R.I.C.
Professor D. W. Mathieson, Ph.D., B.Sc., F.R.I.C.
G. F. Phillips, M.Sc., F.R.I.C.
R. F. Porter, B.Sc., F.R.I.C.
*B. A. Rose, A.R.I.C., A.R.C.S.
E. W. Summers, B.Sc., L.R.I.C.

Secretary to the Committee: E. S. Greenfield

* Resigned, October 1966

Pharmacognosy Subcommittee A

Chairman: Professor J. W. Fairbairn, D.Sc., Ph.D., B.Sc., F.P.S., F.R.I.C., 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.
K. R. Fell, B.Pharm., Ph.D., F.P.S.
A. J. Feuell, Ph.D., B.Sc., A.R.I.C.
D. C. Harrod, B.Sc., F.P.S., F.L.S.
Betty P. Jackson, Ph.D., B.Pharm., B.Sc., F.P.S.
J. M. Mitchell, F.P.S.
M. H. Ransom, B.Pharm.
Professor J. M. Rowson, Ph.D., M.Sc., F.P.S., F.L.S.
G. R. A. Short, F.P.S., F.L.S.
Professor G. E. Trease, D. de l'U., B.Pharm., F.P.S., F.R.I.C., F.L.S.
A. A. Williams

Secretary to the Committee: Pamela M. North

Pharmacognosy Subcommittee B

Chairman: Professor J. M. Rowson, Ph.D., M.Sc., F.P.S., F.L.S.

A. J. M. Bailey, B.Sc., F.P.S., F.R.I.C.
D. Holness, B.A.
Wm. Mitchell, Ph.D., B.Sc., F.R.I.C.
W. D. Raymond, O.B.E., Ph.D., B.Sc., F.R.I.C.
E. J. Shellard, Ph.D., B.Pharm., F.P.S., A.R.I.C., F.L.S.

Secretary to the Committee: Pamela M. North

PHARMACOGNOSY SUBCOMMITTEE C

Chairman: D. C. Garratt, D.Sc., Ph.D., F.R.I.C.

G. J. W. Ferrey, B.Sc., F.R.I.C.
C. A. MacDonald, B.Sc., F.R.I.C.
R. G. Minor, F.P.S., F.R.I.C.
N. Nix, B.Sc., F.R.I.C.
Hilda M. Perry, M.Sc., F.R.I.C.
E. W. Summers, B.Sc., L.R.I.C.

Secretary to the Committee: E. S. Greenfield

PHARMACY SUBCOMMITTEE A

Chairman: H. Davis, C.B.E., Ph.D., B.Sc., F.P.S., F.R.I.C.

H. S. Bean, Ph.D., B.Pharm., F.P.S.
G. M. Burnett, F.P.S.
G. Bryan, F.P.S.
J. O. Davidson, F.P.S., D.B.A.
A. E. Davis, B.Pharm., F.P.S.
A. G. Fishburn, F.P.S., D.P.A., F.R.I.C.
D. N. Gore, F.P.S., F.R.I.C.
J. W. Hadgraft, F.P.S., F.R.I.C.
H. Hoyle, F.P.S.
K. A. Lees, F.P.S., D.B.A.
Christobel E. Mozley-Stark, M.B.E., F.P.S.
A. W. Newberry, F.P.S.
J. R. Phillips, F.P.S.
J. W. Soulsby, F.P.S., D.B.A.
G. Smith, B.Sc., F.P.S.
G. R. Wilkinson, F.P.S.

Secretaries to the Committee: Bridget J. Dean; K. B. K. Davis

PHARMACY SUBCOMMITTEE B

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

A. W. Baker, M.P.S., D.B.A.
H. S. Bean, Ph.D., B.Pharm., F.P.S.
J. P. Curtis, M.P.S.
A. W. Newberry, F.P.S.
Professor D. A. Norton, B.Sc., F.P.S., D.B.A., A.C.T.
W. J. W. Price, F.P.S.
G. Smith, B.Sc., F.P.S.
G. R. Wilkinson, F.P.S.

Secretaries to the Committee: Bridget J. Dean; 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
E. Fawcitt, F.P.S.
*T. F. Foulkes, A.M.C.T., A.T.I.
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.
Christobel E. Mozley-Stark, M.B.E., F.P.S.
J. A. Myers, B.Pharm., F.P.S., LL.B., D.P.A., F.C.C.S.
S. J. Relph, B.Pharm., F.P.S., F.L.S.
R. Robinson, A.T.I.
R. Maxwell Savage, Ph.D., M.A., F.R.I.C.
J. T. Scales, M.R.C.S., L.R.C.P.
D. E. Seymour, B.Sc., F.R.I.C.
D. J. W. Taylor, B.Sc., M.B., Ch.B., D.P.H., M.I.H.

Secretary to the Committee: Pamela M. North

*Resigned, February 1967

STERILISATION PANEL. A. Bishop, F.P.S.; P. Harbord, A.I.M.C.T.; J. A. Myers, B.Pharm., F.P.S., LL.B., D.P.A., F.C.C.S.; R. Maxwell Savage, Ph.D., M.A., F.R.I.C.; J. T. Scales, M.R.C.S., L.R.C.P.; K. Tattersall, B.Sc.

Members of the staff of the Department of Pharmaceutical Sciences have assisted in the preparation of the British Pharmaceutical Codex 1968. G. R. Brown, B.Pharm., B.Sc., F.P.S., K. B. K. Davis, M.P.S., Bridget J. Dean, B.Pharm., M.P.S., E. S. Greenfield and Pamela M. North, B.Pharm., M.P.S., have acted as secretaries to the committees and assisted with editorial work, while J. C. Deavin, B.Pharm., M.P.S., and Barbara Gartside, B.Pharm., M.P.S. carried out analytical investigations, and W. Lund, F.P.S. investigated formulation problems in the laboratories of the department. Delia E. Baldrey, H. C. Happold, M.P.S. and R. Keenan also assisted in the preparation of the text, and Edith C. Condon and Maureen A. Dempsey read some of the proofs.

The Codex Revision Committee acknowledges the invaluable assistance and advice received from government departments, from professional institutions and other organisations, including the Association of the British Pharmaceutical Industry, the British Standards Institution, the Commissioners of Customs and Excise, the Ministry of Health, the Home Office (drugs branch), the Laboratory of the Government Chemist, the Medical Research Council, the National Pharmaceutical Union, the Proprietary Association of Great Britain, the Royal Botanic Gardens, Kew, and the Society for Analytical Chemistry. The advice of overseas authorities, such as the Department of Health, Australia, and the Department of National Health and Welfare, Canada is also gratefully acknowledged.

Various experts have contributed information on special points and have given valuable advice, including C. N. Armstrong, A. J. Bowdler, D. A. Cahal, C. E. Dent, R. Goulding, D. R. Laurence, J. G. G. Ledingham, W. A. Little, B. G. B. Lucas, K. A. Newton, E. E. Pochin, T. A. J. Prankerd, B. N. C. Prichard, H. R. Roberts, G. A. Rose, M. L. Rosenheim, R. G. Todd, T. E. Wallis and W. F. White.

A number of pharmacists assisted by preparing and commenting on products made according to new and amended formulae, including J. D. Appleton, M. A. Ellis, J. W. B. Fish, S. Gaffney, J. Hall, W. Mott, L. Stocks, and H. T. Thomas.

The Codex Revision Committee is co-operating with other authorities in the preparation of a European Pharmacopoeia, to be published under a convention signed by the governments of Belgium, France, West Germany, Italy, Luxembourg, Netherlands, Switzerland and the United Kingdom. It is intended that from the date of coming into effect of the European Pharmacopoeia, the standards in its monographs for any article shall become the standards in the United Kingdom for that article when used in the practice of medicine, surgery or midwifery. In other countries in which the British Pharmaceutical Codex is used the competent authorities should decide whether the standards of the European Pharmacopoeia shall apply in their territories.

此为试读,需要完整PDF请访问: www.ertongbook.com

Introduction

The British Pharmaceutical Codex fulfils two important functions, namely to give information on drugs and other pharmaceutical substances, and to provide standards for a range of substances and materials that are not included in the British Pharmacopoeia. New and effective drugs are introduced into medical practice every year, and it is desirable that authoritative information on those substances should be made available as soon as practicable after they become established. That information the Codex attempts to provide. In order to accommodate those new monographs while keeping the size of the book within reasonable limits, it is necessary to omit from each new edition as many as possible of the monographs on the older and less frequently used drugs and pharmaceutical adjuvants. In preparing this ninth British Pharmaceutical Codex, the criteria for inclusion of monographs have been widened, and the Codex Revision Committee has been able to consider for inclusion any drug which is in sufficiently wide use for a published standard to be desirable, irrespective of the therapeutic merit of the drug in question. The committee has included a number of monographs on account of the particular therapeutic interest of the substances described. Monographs on several pharmaceutical adjuvants which are used as emulsifying agents, tablet disintegrants and binders, etc., have also been added to this edition. Those materials are widely employed in formulated preparations and it is desirable that their quality should be adequately controlled; the Codex monographs are designed for that purpose.

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

Part I: Drugs and Pharmaceutical Adjuvants. This part has increased in size, 75 monographs having been deleted and 97 added. The majority of the new substances are antibacterial agents (both antibiotic and chemotherapeutic) and substances that affect the central nervous system. A number of new diuretics have also been added, as well as anthelmintics, synthetic corticosteroids, hormones and vitamins. The new monographs on pharmaceutical adjuvants include: aluminium magnesium silicate, a suspending and stabilising agent; alginic acid, microcrystalline cellulose and povidone, which are commonly used excipients in the manufacture of tablets; the preservatives sorbic acid and potassium sorbate; hypromellose, a thickening agent used for various purposes, including the thickening of eye-drops; cellacephate, which is used as an enteric coat for tablets; and some well-known emulsifying agents derived from sorbitan. The standard for titanium dioxide has been revised to ensure that the material is suitable for internal as well as external use.

The information on the action and uses of drugs differs from that in most other reference books in that it has been prepared, after discussion

of published evidence and private experience, by members of a subcommittee of medical and pharmaceutical experts. In addition to providing statements for drugs included in the Codex for the first time, the subcommittee has re-examined all existing statements and, where necessary, has amended them to take into account fresh evidence or altered practice. In order to accomplish this extensive revision within the time available, much of the preliminary work has been done in small working groups which have sifted available information and, when necessary, consulted other experts who are not members of the subcommittee. For the convenience of readers seeking information quickly, the necessary details are set out under appropriate headings, such as action and uses, undesirable effects, precautions and contra-indications, poisoning, and dose. The action, uses and posology statements have been considerably revised, due note having been taken of the current interest in drug interactions and adverse reactions. In a number of instances, the statements of posology have been given in greater detail than in the past, and doses for children have been added in some cases. In many monographs, it has been found preferable to refer the reader to the posology and treatment given under "action and uses" rather than to state a simple range of doses under "dose". In appropriate monographs, definitions of drug dependence have been included; those are based upon the work of N. B. Eddy, H. Halbach, H. Isbell and M. H. Seevers, *Bull. Wld Hlth Org.*, 1965, **32**, 721–33. In conformity with the recommendation of the World Health Organisation expert committee on dependence-producing drugs, the use of the term "addiction" has been abandoned.

Information on the commercially available dosage forms of all drugs has been extended, but it should be understood that only the more usually prescribed strengths of preparations containing a single active ingredient are indicated and the availability may have changed since the time (March 1968) that the text went to press.

The new specifications given under the heading "Standard" are based largely upon suggestions from manufacturers, who, as in the past, have greatly assisted the subcommittees. The specifications of all substances retained from the previous Codex have been examined and, where necessary, revised. The assay for anthraquinone glycosides in Senna Leaf is based on a method recommended by the Joint Committee of the Pharmaceutical Society and the Society for Analytical Chemistry on Recommended Methods for the Evaluation of Drugs (*Analyst*, 1965, **90**, 582). Members of the subcommittees and the Society's own laboratory have also carried out experimental work in developing new methods and standards; with a few exceptions, all new tests, whatever their source, have been examined in the Society's laboratories.

Part II: Immunological Products and Related Preparations. The information on immunological products and related preparations has been completely revised, and the monographs on typhoid-paratyphoid vaccines have been combined and presented as a single monograph. The recommendations on the immunisation of children and of travellers have been amended to conform to current practice.

Part III: Preparations of Human Blood. The information in this section has been brought into line with present-day requirements. The monograph on Human Normal Immunoglobulin Injection (formerly Human Gamma Globulin Injection) now contains information on the preparation made from the blood of donors immunised against tetanus.

Part IV: Surgical Ligatures and Sutures. The revision of this section of the Codex has been influenced to a marked degree by the shadow of overriding standards being prepared by a Group of the European Pharmacopoeia Commission and the possibility that they may come into effect during the life of this Codex (see Preface). In an attempt to minimise the need for drastic changes spread over a short period at some future date, the Ligatures and Sutures Subcommittee has attempted to anticipate the requirements of the European Pharmacopoeia as far as possible, and, as a step in this direction, metric size designations have been introduced for non-absorbable sutures, to complement the existing B.P.C. gauging system. While the sizes for stainless steel sutures follow those laid down in British Standard 4106:1967 for Surgical Stainless Steel, a slightly different series has been adopted for the other non-absorbable sutures in an attempt to meet the present reputed preferences of surgeons for particular sizes.

The Revision Committee has accepted representations that the non-toxicity of polyamide 6 (nylon 6) is such that it may be used for polyamide sutures, which hitherto have been restricted to polyamide 6/6. Pending the development of a more specific test for unpolymerised material, caprolactam is limited by a test for water-soluble extractive.

Because of the difficulties of finding suitable colouring materials, the colour coding adopted in 1963 to distinguish sizes of nylon sutures has been abandoned by the Revision Committee, although any manufacturer who wishes to adopt a similar or different scheme for his own products will not be prevented from so doing by the present requirements.

As explained below, the titles of sterile non-absorbable sutures, like those of sterile dressings, have been modified, the descriptive term "Sterilised" having been replaced by "Sterile".

Part V: Surgical Dressings. The contents of this part have been revised and a number of dressings which are of diminishing importance or no longer available have been deleted, notably certain rayon dressings. In order to conform with the recommendations made by a panel set up by the Surgical Dressings Subcommittee to study the sterilisation of dressings, the use of the term "sterilised" has been abandoned, and the word "sterile" has been adopted for the labelling of those dressings which have been subjected to a properly performed sterilisation procedure, are appropriately wrapped and are expected to comply with the tests for sterility.

For many years, it has been realised that the standards which have been set for certain woven dressings are not entirely satisfactory. The Codex standard is set with the fact in mind that it shall apply to an isolated individual sample taken at any stage between the manufacturer and user. In order to be certain that such a sample will comply, a manufacturer needs to work to much closer tolerances than those set in the standard, but

because he has available a very large number of samples, it is possible for him to assess more accurately the overall quality of his product. During the two previous revisions, attempts were made to relate the Codex standards in respect of thread counts to the number of samples available for testing, but it had not been possible to devise a generally accepted scheme. In the present Codex, such a scheme has been introduced for Open-wove Bandage, Unbleached Calico, Absorbent Gauze and gauze tissues, and Absorbent Lint, and if this proves acceptable it is proposed to extend the scheme to other suitable dressing fabrics in a future Codex.

As in other parts of the book, the revision has effected a change from the Imperial to the metric system whenever possible. Notably, the Standard Dressings are now defined in terms of metric quantities, while the internationally accepted unit, the TEX, is introduced for yarn counts.

After many abortive attempts in the past to introduce a test for adhesiveness, a suitable test has at last been devised by the Technical Subcommittee of the Conference of Medical and Surgical Adhesive Plaster Manufacturers, but the development of an acceptable method for the determination of belladonna alkaloids in Belladonna Self-adhesive Plaster has still not been achieved.

Part VI: Formulary. As most people who consult the Codex are now well accustomed to the use of titles of the form "Phenobarbitone Tablets", these have now been adopted as main titles and the inverted forms (such as Tablets of Phenobarbitone) no longer appear at the head of the monographs, although, as stated in the General Notices, the previous main titles are still acceptable for labelling and other purposes. Notwithstanding this change, the position of a monograph in this section of the book remains unaltered, all preparations being in alphabetical order following the general monographs on the class to which they belong. In conformity with the British National Formulary policy, preparations intended for children are now called "paediatric", and the expression "for infants", which was formerly used, has been abandoned; thus any misunderstanding as to the meaning of the term "infant" is avoided.

Hitherto, only in the case of injections and tablets have monographs been included in the Formulary if the full formulation is not known or if the active ingredient is not freely available to pharmacists in general and hospital practice. There are on the market very many, widely prescribed proprietary products of other classes of preparations, and, because of that policy, it has not been possible in the past to include monographs on them in the Codex. The Revision Committee considered it desirable that published standards should be available for such products, and it has consequently amended the criteria governing the inclusion of monographs in this section of the book. As a result, there are now monographs included in the Codex for a number of creams, ointments and oral preparations, together with a few other products, in which full details of the formulation are not given.

As a result of this change in policy and the consequent wider range of proprietary products described in the Codex, it has been found necessary to review the titles of liquid oral preparations and revise the definitions of Elixirs, Mixtures and Syrups in order to ensure that products of a similar

nature are included in the same class of preparation. There are, for example, a number of proprietary products which are described by their manufacturers as Oral Suspensions, but, although this title is accepted in the United States Pharmacopoeia, Pharmacy Subcommittee A decided that it was unnecessary to introduce a new class of preparation, as those products would fall naturally in the class of Mixtures if the definition of that class were altered slightly. The Subcommittee also considered that, except for one or two traditional medicated syrups which are really only formulated for convenience in dispensing, the title Syrup should be restricted to syrups used as a vehicle or for flavouring and that those proprietary products that are so named should be included in the Codex as elixirs if the liquid were clear and as mixtures if the product were a suspension. In order to ease any difficulties that might arise from this arrangement, a synonym has been included in each monograph on those preparations which correspond to proprietary products bearing a different class name. These amendments have resulted in the need to change the titles of a few existing monographs; for example, Phenethicillin Syrup of the 1966 Supplement is now Phenethicillin Elixir, and Tetracycline Elixir, which is brought into the Codex from the British National Formulary 1966, has become Tetracycline Mixture, although the former titles are still included as a synonym. It is to be hoped that manufacturers of ethical proprietary products will bear the revised definitions in mind when naming new products, so that some of the confusion resulting from different class titles having been applied to similar types of product might be avoided and a change in the class name will not be necessary if it is subsequently decided to include a monograph on the product in a future Codex.

The conversion of formulae to the metric system, which was begun in the 1963 Codex and continued in the 1966 Supplement, has been completed in this edition. Each preparation so reformulated has been examined in the Society's laboratory and many have been made and commented upon by pharmacists in general practice. As a result of those comments, some of the formulae originally proposed were modified in order to produce more satisfactory preparations. In most instances, the opportunity has been taken to provide recipes which will result in the weighing and measuring of convenient quantities for those preparations which may be prepared extemporaneously, but for a few complicated traditional formulae, which are usually only prepared on a large scale anyway, an almost precise metric equivalent of the Imperial quantities has been retained, chiefly to avoid the possibility of increasing an existing instability or impairing the stability of a satisfactory preparation. The dose volumes have been restricted to 5 millilitres (for most elixirs, paediatric mixtures and linctuses), 10 millilitres (for adult mixtures) and 50 millilitres (for draughts). In many cases, this has resulted in the concentration of active ingredient in the preparation made to the metric formula being significantly different from that of the 1963 preparation. The amounts of substances now included in the preparations for pharmaceutical purposes, e.g. flavourings, colourings, antoxidants, etc., are based, not on their proportions relative to the active ingredient(s), but on their concentration in the former Imperial preparation.

A few oral proprietary products which have been included in the Codex for the first time have a dose volume which is not 5 or 10 millilitres, and those may require dilution by the pharmacist so that they can be measured in units of 5 or 10 millilitres for the patient. Even with those products that have been reformulated, the dose for a young child may, in some cases, be less than 5 millilitres and those preparations also will require dilution. The directions necessary for the dilutions are included in the appropriate monographs.

Clinical experience suggests that the concentration of active ingredient in several proprietary ointments and creams containing an anti-inflammatory synthetic corticosteroid may be unnecessarily high for the treatment of certain conditions. In order to assist those pharmacists who receive prescriptions for strengths lower than any available from a manufacturer, suitable diluents are stated in the relevant monographs.

Since the publication of the 1963 Codex, considerable development work has been carried out, both by members of Pharmacy Subcommittee B and in the Society's laboratory, on the formulae for eye-drops. New recipes were published in the 1966 Supplement, and those formulae have again been revised where necessary in the light of further experimental work and comments expressed by patients using the Supplement eye-drops.

Requirements for sterility have been introduced for eye ointments, so that all ophthalmic preparations in the Codex are now required to be sterile. The publication of a British Standard (B.S. 4230:1967) for collapsible metal eye-ointment tubes has enabled a statement on metal particles to be included in the general monograph on Eye Ointments which should be more generally acceptable than that in the 1963 Codex. Consideration will be given in the next Codex to the possibility of including a limit for metal particles in the Standard for eye ointments.

Late in this revision of the Codex a request was received that a monograph should be included on a contact-lens solution. Enquiries by Pharmacy Subcommittee B revealed the existence of a number of proprietary products, some of which were offered as storage solutions and others as wetting solutions. From a consideration of the composition of these products, the subcommittee concluded that none of the solutions was likely to be entirely satisfactory for both purposes, and many seemed unlikely to match up to the requirements which the subcommittee considered essential in such a solution, particularly as regards bacteriological cleanliness. Discussions with ophthalmic consultants have established what is required of such a dual-purpose solution, but lack of time prevented the formulation of a suitable preparation and its subsequent testing, in both the laboratory and clinical practice. This work is continuing, however, with a view to publishing a suitable formula in a Supplement. Subsequent to the completion of the committee's work for the 1968 Codex, it was realised that Hypromellose Eye-drops, a new preparation introduced to meet the need for "artificial tears", appeared to fulfil most, if not all, of the criteria for a dual-purpose contact-lens solution, except that possibly its viscosity might be too high for some users. It is suggested, therefore, that these eye-drops might be tried in the meantime for that purpose, and directions are included in the monograph on Hypromellose Eye-drops for adjusting the

此为试读,需要完整PDF请访问: www.ertongbook.com