BRITISH PHARMACEUTICAL CODEX 1963

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The Council of the Pharmaceutical Society of Great Britain recommends that the British Pharmaceutical Codex 1963 come into force in the United Kingdom on January 1, 1964. It is open to overseas authorities to fix such dates as are convenient to them.

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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, and 1959. 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 scope of the book has remained unchanged, and the general format of the subsequent issues has been continued in this, the eighth Codex, which has been prepared, as on previous occasions, by the Codex Revision Committee at the direction of the Council of the Pharmaceutical Society.

At the request of the British Pharmacopœia Commission the Council agreed in 1959 that in future the publication of the Codex would coincide with that of the British Pharmacopœia, so that new versions of the two books could come into effect on the same dates. This arrangement makes it easier to provide continuing current standards for those substances and preparations that are omitted from the Pharmacopœia and subsequently included in the Codex. Very close co-operation between the Commission and the Revision Committee has been necessary in order to provide comparable standards under these circumstances, 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 each alternate new issue of the British National Formulary will also come into effect on the same dates as the Pharmacopœia and the Codex. With all three books becoming effective at the same time, the issue of amendments to the Codex and British National Formulary that have hitherto been necessary on the publication of a new Pharmacopœia will be avoided. The introduction of this new arrangement has meant that only $3\frac{1}{2}$ years has elapsed since the publication of the seventh Codex in 1959. Because of the short interval between these latest editions, there has been no Supplement to the British Pharmaceutical Codex 1959.

Since the reconstitution of the Codex Revision Committee in January 1960, intensive work has been carried out by the Committee and its eleven subcommittees. The scope of the book remains unaltered and every effort has been made to ensure that the Codex will continue to enjoy a high reputation as a reference book and as a source of standards for drugs and their preparations, pharmaceutical adjuvants, surgical dressings and sutures not included in the British Pharmacopœia.

The fact that the period that has elapsed since the publication of the previous book is shorter than usual has made the task of the Codex Revision Committee and its subcommittees, particularly that of the Action and Uses Subcommittee, the Formulary Standards Subcommittee and the Pharmacognosy Subcommittee C, extremely arduous and demanding, and the Council of the Pharmaceutical Society acknowledges its great indebtedness to all committee members for the expert knowledge and valuable time that they have so freely given. The membership of the Codex Revision Committee is given on p. viii and that of the subcommittees is given in the following pages.

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Members of the editorial and laboratory staff of the Department of Pharmaceutical Sciences have assisted in the preparation of the British Pharmaceutical Codex 1963, particularly G. R. Brown, B.Pharm., B.Sc., F.P.S., Joan M. Denney, M.P.S., Barbara Gartside, B.Pharm., M.P.S., Joan M. McKay, B.Sc., M.P.S., Jill B. Rock, M.P.S., and G. Smith, B.Sc., F.P.S.; D. Booth and Edith C. Condon also assisted in the preparation of the book.

The invaluable advice and assistance received from government departments, from professional associations and other organisations, including the Association of British Pharmaceutical Industry, the British Standards Institution, the Commissioners of Customs and Excise, the Laboratory of the Government Chemist, the Medical Research Council, the Ministry of Health, the Royal Botanic Gardens, Kew, the Society for Analytical Chemistry, and from individual firms is gratefully acknowledged by the Codex Revision Committee.

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Introduction

The British Pharmaceutical Codex fulfils two important functions, namely to give information on drugs and other pharmaceutical materials, and to provide standards for a range of substances that are not included in the British Pharmacopœia. Many new and valuable drugs are introduced into medical practice each year and it is desirable that information on these substances should be made available as soon as practicable after they become established. This information the Codex attempts to provide. In order to accommodate these 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 materials. In selecting substances to be described in this eighth edition of the British Pharmaceutical Codex, the Codex Revision Committee has been guided by the same principles as were adopted for the previous edition: drugs and their preparations are included either on account of their accepted value in medical practice, or because, while no longer accepted as being necessary by many medical and pharmacological authorities, they obviously have the confidence of a large number of medical practitioners and are so widely used that a standard and information on their use are desirable. The changes in the contents from the previous edition are listed on pp. xxi to xxvii. The general format of the seventh edition has been retained, and because of the increased amount of new information included, Parts I to VI now occupy 110 additional pages.

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

Part I. As well as monographs on more than 120 new drugs, several new monographs on substances used for pharmaceutical formulation have been added, including sodium carboxymethylcellulose, which is used as a suspending agent, and phenylethyl alcohol and sodium edetate, which are used in preserving and stabilising certain preparations. In addition, the monographs on dimethicone and methylcellulose which appeared in the previous edition have been extended to cover various grades. The increasing use of pressurised packs and of skin-cooling sprays has led to the introduction of monographs on three halogenated hydrocarbons commonly used as aerosol propellents and refrigerants.

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. Statements have been prepared for all the new monographs and the remainder have been reexamined, and, in most cases, amended to take into account new evidence or altered practice. Information on the available dosage forms of all drugs has been extended.

In monographs retained from the previous edition, specifications given under the heading "Standard" have been amended where experience with, or modification of, the materials has shown such amendments to be desirable, and similar specifications have been prepared for all new drugs that are not also the subject of monographs in the British Pharmacopœia 1963. Many of the specifications are based upon suggestions from pharmaceutical manufacturers who, as in the past, have greatly assisted the subcommittees. Members of the subcommittees have themselves carried out much experimental work in developing methods and standards. With a few exceptions all new and amended tests and assays have been confirmed in the Society's laboratories, which have also been concerned in the development of new methods. During the course of the revision an attempt has been made to replace nitrogen determinations and other non-specific methods of assay by more specific techniques where these are available.

The introduction of increasing numbers of related compounds having very similar chemical structures has led to the introduction of infra-red spectrophotometric methods for distinguishing between the compounds and confirming their identity. The subcommittees on pharmaceutical chemistry first considered providing graphical representations of typical spectra for use in identification tests, but this was abandoned when it was shown that the variation in resolving power, even between spectrophotometers of the same type, could make this method of comparison with standard spectra unreliable. It is therefore necessary in each case to make a comparative test with a specimen of material, the identity of which has already been established. Infra-red spectrophotometric identification tests are described in the British Pharmaceutical Codex for the following substances: ferrous fumarate (identification of the isolated fumaric acid), norethynodrel, prednisolone sodium phosphate, spironolactone, sulphadiazine sodium, sulphadimethoxine, sulphaguanidine, sulphanilamide, sulphaphenazole, sulphathiazole, triamcinolone, and triamcinolone acetonide. Information has been exchanged with the World Health Organisation, which distributes specimens of certain chemicals through its Centre for Authentic Chemical Substances. Specimens of the above materials are not available from the WHO Centre at the present time, and the Pharmaceutical Society of Great Britain is therefore making arrangements to supply authentic specimens of the necessary substances to analysts who require such specimens to carry out the identification tests.

An improved method has been introduced for the determination of lead in bismuth compounds, and the limits have been amended to take into account the greater sensitivity of the method. The new assay methods included for the rauwolfias and for capsicum and its preparations are based on methods recommended by panels of the Joint Committee of the Pharmaceutical Society and the Society for Analytical Chemistry on Methods of Assay of Crude Drugs. The increased work required in standardising potent crude drugs and preparations of vegetable drugs has resulted in the formation of a new committee (Pharmacognosy Subcommittee C) to undertake this work.

Part II. The information in this section on immunological products and related preparations has been completely revised. The monographs on old tuberculin and tuberculin purified protein derivative that appeared in the previous edition have now been combined under the title "Tuberculins" for convenience of users. Schedules for the immunisation of children and of travellers have been included in the general monograph on vaccines.

Part III. Comparatively little change has been necessary to this section, which deals with preparations of human blood.

Part IV. The range of surgical ligatures and sutures covered by this section has been extended by the inclusion of new monographs on various types of polyester and stainless steel suture, and amendments have been made to the existing standards to bring them into line with current practice.

Part V. This section on surgical dressings has been extensively changed and a number of noteworthy amendments have been made. New monographs are included for three plastic first-aid dressings, which differ in the extent to which they allow transmission of water, air and water vapour, and for the plastic self-adhesive plasters used in their construction. Also described and standardised for the first time are gauze pads (perhaps better known as swabs or sponges) made of either cotton or rayon, either plain or incorporating a radio-opaque member which enables any pad left inadvertently in the body when the wound has been closed during a surgical operation to be detected radiologically. Because of the doubtful availability of oiled rayon, a monograph on oiled silk, which was omitted from the previous edition, has been reinstated.

An innovation is the inclusion of short general statements on the uses of most dressings described in the Codex in the belief that these will be of value to users of the book, who, in many instances, have been guided by custom in their choice of a dressing for a particular purpose.

Considerable discussion has taken place during this revision on the function of antiseptics in medicated dressings and the desirability or otherwise of their presence. It has been suggested that antiseptics help to maintain the sterility of sterilised dressings before they are used and may assist in preventing micro-organisms from gaining access to a wound when the dressing is in place, although it is recognised that this latter possibility is doubtful in the case of those antiseptics that are inactivated by body fluids. In response to a request from the subcommittee, the Medical Research Council expressed the opinion that the inclusion of antiseptics is not necessary in first-aid dressings for use under normal conditions where the patient will receive prompt medical attention, but that medication with an antiseptic is desirable when dressings are used on wounds which may not receive medical attention for some time, as may be the case in the overseas armed services. Another expert expressed the opinion that it was preferable for the sterility of a dressing to be maintained by suitable packaging rather than by the incorporation of antiseptics, and that the inclusion of some antiseptics might, in certain circumstances, interfere with tissue metabolism. A diversity of opinions was expressed, both in and out of committee, and a compromise has been adopted. The inclusion of

an antiseptic in the first-aid dressings has been continued, but the antiseptics used have been revised and their number reduced; a notable exclusion is boric acid. If, however, the dressings are sterilised and individually wrapped, the antiseptic may be omitted. It is considered that published information on all aspects of this subject is very meagre, and that the matter is of sufficient importance to warrant an extensive investigation under the ægis of an authoritative medical body.

Because of difficulties which have occurred in interpreting the requirements for foreign matter in certain standards, a statement has been inserted in the general monograph explaining the difference between foreign matter and added foreign matter.

In the standards for certain dressings in the previous Codex, a statement was included requiring that a water-repelling treatment be applied to the dressings if the weft was more than one-third rayon. This was considered essential in order to overcome the loss in strength which occurs when rayon becomes wet, but experience has shown that the treatments generally applied are ineffective. This requirement has not been retained, as it is now considered that even if the wet strength does decrease, the dressings are still sufficiently strong for the purposes for which they are required.

For qualities of dressings that are expressed in terms of weight, the standard is now given in metric quantities, although the approximate Imperial equivalents are given for information. In the case of requirements for cloth construction, however, the Imperial standards are retained, because these are customarily used in the textile industry, but approximate metric equivalents are included for information.

There is now no apparent reason why the amounts of zinc oxide in self-adhesive plasters and bandages should differ in the various dressings. Consequently these monographs have been amended so that the adhesive masses all contain 10 per cent of zinc oxide.

The assay included in the previous edition for the determination of total alkaloids in plasters containing belladonna extract has been reported to give unreliable results. Attempts to improve the method or to provide an alternative have so far been unsuccessful. Investigation of this problem is being continued, but it has been necessary to include monographs without a standard for the alkaloidal content of the adhesive mass for these dressings. It has been possible, however, as a consequence to the development of an assay for capsicum, to include a method for the determination of capsaicin in capsicum cotton wool.

Part VI. The policy governing inclusion of monographs in the formulary section is the same as that in the previous edition; new formulæ are added only if the substances named in them are freely available to pharmacists. Many new drugs are not so available and can be obtained only in the form of one or more formulated products of a single manufacturer. There is usually little point in including formulæ in these circumstances, since there is the possibility that in the first few years that a drug is on the market experience in its use may convince the manufacturer that changes in the character and content of preparations of the drug are necessary or desirable. However, a number of new preparations which are likely to be

prescribed frequently have been included, and information on the development of some of these formulæ is included in the following papers: G. Smith and J. I. Mitchell, *Pharm. J.*, i/1962, 137 (paracetamol elixir); Pharm. Soc. Lab. Rep., *Pharm. J.*, ii/1961, 187 (sulphonamide mixtures).

When it was learned at the beginning of the current revision that the British Pharmacopœia Commission intended to abandon the use of the Imperial system of weights and measures in the forthcoming British Pharmacopœia, the Codex Revision Committee decided to recommend that this system should also be discontinued in the Codex. In the 1959 Codex, some types of preparation, notably injections, were formulated only in the metric system. It was apparent, however, that there would be insufficient time during this revision for the necessary experimental work and careful storage tests to be carried out on all the other formulations. It was therefore decided that for the 1963 Codex reformulation, in which metric weights and measures only are used to define the composition of the preparation, would be confined to certain solid unit-dosage forms, namely lozenges, pastilles, pessaries, suppositories and tablets; pills and solution-tablets are still formulated in both the Imperial and metric systems. It is proposed to complete the reformulation of the remaining preparations in a subsequent edition. Nevertheless, in order to avoid the necessity for early changes to new liquid preparations, these have been formulated in the metric system. It is recognised that the decisions taken have unavoidably resulted in some apparent anomalies in this Codex, but these should be resolved when the change-over is complete. For example, 4 millilitres is accepted in the Codex as the metric equivalent of a dose of 60 minims (one teaspoonful). However, the Codex Revision Committee has decided that when liquid preparations are reformulated in the metric system, 5 millilitres will be regarded as equivalent to the volume of a domestic teaspoon. Consequently, new linctuses, for example, are formulated so that a suitable dose is contained in 5 millilitres, whereas for those linctuses still formulated in the Imperial system the dose is contained in 4 millilitres, or a multiple or fraction thereof. It is clear that after the British Pharmaceutical Codex 1963 has come into effect it will be some time before stocks of unit-dosage preparations formulated in Imperial strengths are used up, and it is to cover the position during this interim period that the statement on corresponding metric and Imperial amounts, which is similar to that made in the British Pharmacopœia, has been included in the General Notices, p.xxxiii.

Important changes have been made in eye-drops. Solution for Eye-drops, which was used as the vehicle for many of the eye-drops in the previous edition, has been omitted, because it has been shown that this solution is ineffective for preventing the growth of bacteria in eye-drops. No single bactericide appears to be appropriate for all aqueous eye-drops, but chlorocresol, in a concentration of 0·05 per cent, has been chosen for the majority of the eye-drops in this edition. The report of the Laboratory of the Department of Pharmaceutical Sciences for 1962 (*Pharm. J.*, i/1963, 378) contains notes on the compatibility of chlorocresol in eye-drops and on the stability of certain eye-drops. It has been recognised for many years that eye-drops should be sterile when they are used and that the ideal