

and elderly users would do well to ensure good light and accurate visual correction if they are to avoid headaches when using it.

## The British Pharmaceutical Codex 1968\*

Reviewed by

EDWARD G. FELDMANN, Ph.D.

*Director of the National Formulary, and Chairman of the NF Board,  
U.S.A. National Formulary*

As a foreigner preparing a review on the latest edition of The British Pharmaceutical Codex, I was sufficiently disturbed, if not alarmed, by the future uncertainties referred to in a recent commentary in The Pharmaceutical Journal (Editorial, 1968), to feel that a discussion of comparable or parallel situations in my own country should preface the review.

United States law (the Federal Food, Drug, and Cosmetic Act, as amended) recognizes as "official compendia" the United States Pharmacopeia and the National Formulary. These two compendia are nonduplicative in content but are very similar in purpose and treatment of subject matter. Between them they serve to establish officially recognized standards of identity, purity, strength, and quality for virtually all therapeutically meritorious articles available for use in the U.S. Neither, however, provides more than the very briefest information on actions, uses, and doses of drugs, and nothing on side-effects, precautions, contra-indications, and so on. Moreover, there is currently no other such compilation in this country which enjoys legal recognition.

A growing desire appears to be developing on the part of various sectors and groups for the creation and issuance of a compendium of therapeutic information. Many plans have been offered by the Commissioner of the U.S. Food and Drug Administration and other interested parties. Several legislative proposals have been introduced into Congress to authorize and direct preparation of such a compendium by a government agency.

This incidental information is offered to demonstrate the need for authoritative information on actions, uses, and doses of drugs of the type presently provided in the United Kingdom by the B.P.C. It suggests that in the absence of such a compendium, the present practice of pharmacy and medicine would require that such a volume be prepared and made available for use by practitioners.

We must not overlook the fact, either, that such a compendium does not come into being simply by legislative decree. A comprehensive, scientifically sound, and medically accurate compilation requires considerable expertise and experience in a broad variety of areas. This must be combined with a special knowledge of the intricacies of committee organization, effective procedure, and productive direction which are comparable to the marshalling of a military force and its successful engagement on the field of battle.

\* *THE BRITISH PHARMACEUTICAL CODEX* 1968. Pp. xxxvii + 1513. The Pharmaceutical Press, London. £7, post free.

In the reviews of the two most previous editions of the B.P.C. (Feldmann, 1960, 1963) emphasis was directed at the suitability of the Codex as a book of standards. We now read that the action of the British government in taking over the British Pharmacopoeia leaves the future of the Codex "a matter of speculation" (Editorial, 1968). Since the matter of standards has been apparently provided for in the new Medicines Bill, our principal attention is naturally drawn to the companion role played by the Codex in the area of providing useful therapeutic information. Historically the Codex has performed so important a function in this field that concern over its possible loss or disappearance is a natural consequence.

Close examination of the 1968 edition reveals that Editor S. C. Jolly, the Codex Revision Committee under the Chairmanship of H. G. Rolfe, and the numerous Subcommittees have admirably discharged the directive and responsibility given them by the Council of the Pharmaceutical Society of Great Britain. The excellence of the new edition is readily apparent to even the most casual reader.

There are five relatively objective methods of judging the quality of a new pharmacopoeia or formulary; these criteria are known to and utilized by those persons intimately involved with such revision and publication programmes. The five criteria are: (a) the perception shown in selection of new drugs for initial inclusion; (b) the wisdom demonstrated in weeding out and discarding drugs no longer worthy of recognition; (c) the technical ability of the scientific bodies in utilizing advanced scientific methods of drug testing; (d) the adoption of more sophisticated types of specifications which will provide greater assurance of drug quality; and (e) the general expertise demonstrated in the application of new specifications and the methods for their determination, as well as the accuracy and general reliability of the information in all areas, including the therapeutic commentary.

The new Codex measures up well when examined and assessed by any of these. There are almost 100 new drug substances including pharmaceutical adjuncts, plus about the same number of new dosage forms, including capsules, creams, elixirs, injections, lozenges, ointments, tablets, and tinctures. The effectiveness of the housecleaning is evident from the list of deletions which include buchu, gall, ipomoea, jalap, lard, linseed oil, mercury, and a few other nostrum-type articles which should have been placed among the discards long ago. Interestingly enough, however, some of the deletions are items of rather recent vintage, and, in addition to indicating the rapid advances of modern therapy, it will be interesting to see what reaction these deletions will generate on the part of those who use and rely upon the Codex.

Chromatography has been widely used with thin-layer and gas-liquid chromatographic methods in particular evidence. The utility of these procedures for small quantities, coupled with their selectivity, as well as their wide applicability to many classes of drugs, more than overcome the somewhat reduced precision associated with the techniques when compared to other quantitative procedures.

The greater emphasis on determination of potential impurities is representative of strides which have been made in applying the new techniques in an effort to provide better standards of purity and quality. While much has been done in this regard, it would be incorrect to imply that more could not yet be done. For example, the National Formulary (U.S.A.), currently in preparation, will introduce atomic absorption spectroscopy for the assay of certain metal-containing compounds, as well as X-ray diffraction for specifying the acceptable polymorphic forms of certain drugs known to exist in more than one form. [While the B.P.C. has introduced a novel infrared procedure for the examination of the crystal forms of chloramphenicol palmitate, recent reports in the research literature (Borka & Backe-Hansen, 1968) indicate that polymorphic transformations may take place not only in solution but even in the solid state under pressure when preparing a potassium bromide pressed

disk. At any rate, infrared spectroscopy appears to be less generally satisfactory for distinguishing polymorphs than X-ray diffraction.]

However, a much more significant difference exists in the standards of the Codex and those of the USP and NF. After a trial period in the 1965 editions of the NF and USP, tests for "content uniformity" are now being widely applied in the monographs for tablets, capsules, sterile solids with diluents, and certain other dosage forms, which will appear in the forthcoming editions of these compendia. These content uniformity tests are based upon the assay of a number of single dosage units and are in addition to the conventional assay of a composite sample—usually 20 tablets or capsules. The excellent review of pharmacopoeial standards and specifications prepared by the Canadian Food and Drug Directorate (French, Matsui & others, 1967) emphasized the desirability of such a test in light of the frequency of poor mixing and other factors which may result in lack of homogeneity in a particular batch or lot.

However, such shortcomings as may exist—such as the lack of content uniformity tests—are few in the new Codex, and it would be an injustice to imply otherwise. Indeed, one must search hard to find any real point of possible criticism.

Perhaps more than in any other respect, the care in preparing and compiling the B.P.C. 1968 is evident in the accuracy of its content. This attentiveness is particularly reassuring to the practitioner in connection with the actions and uses information. In this respect little can be added by way of additional praise to that stated in the early paragraphs of this review.

In conclusion, B.P.C. 1968—which is scheduled to become effective or "to come into force" on March 3, 1969—is not only a worthy addition to the series, but indeed represents a new high water mark from the standpoint of its overall excellence. In the expectation that many practitioners and others will find it to be an eminently useful text, it is respectfully suggested to the reader that he preserve his copy with due care; the uncertainties voiced concerning the future of the Codex make it appear that the 1968 edition may have to serve his purposes for many, many years to come!

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