PHARMACOPOEIAS AND FORMULARIES

THE BRITISH PHARMACOPOEIA 1963*

REVIEWED BY LLOYD C. MILLER, PH.D.
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THE "B.P. 1963" has appeared, on schedule, five years after publication of the revision it supersedes. Within its familiar red covers is satisfying and solid evidence of a truly large-scale voluntary effort and exceptionally good administrative direction. It is the ninth revision of the first British Pharmacopoeia, which appeared in 1864, and thus becomes the centenary edition. Greater significance attaches to holding now to a five-year schedule when attention is drawn to the fact that only five revisions had appeared by 1948.

The Secretary's office aids reviewers, among others called upon early to look closely at each new revision, with a discussion in the Introduction of "the principal changes made" in the new edition. In this way, those nearest the revision have a means of ranking the importance of the changes brought about. The topic given the greatest attention in the Introduction is the full achievement of the change-over from the Imperial system to the metric system of weights and volumes. The many complex problems met in dealing with this conversion are considered in detail. A reference is made to the careful advance preparations in the form of the announcement in B.P. 1958. They received other publicity as well. The older forms of penicillin are the subject of a further systematic change in potency declaration represented in the virtual abandonment of activity units in favour of metric units in stating dosage.

The introduction notes also an important inclusion, in many monographs of a brief statement under the heading "Action and Use". Experience elsewhere suggests that this will prove to be a most welcome aid to the users of the new compendium. However, "The statements are in no sense intended as a complete guide to the use of the substance (see General Notices, page 9). The information is not usually repeated in the monographs on preparations of the substance and in some instances it has been found more convenient to include the information under the statement on 'Dose'."

Of the many changes that strengthen the standards in the individual monographs, those that affect capsules as a group provide, for the first time, limits on disintegration and uniformity of weight of the contents. Permission to add colours to capsules is granted in a few cases, albeit reluctantly, inasmuch as the Commission goes on record as being of the opinion that "the practice of colouring preparations may have serious disadvantages and should be exercised with restraint".

A significant change in the approach to standards is represented by the case of Phenobarbitone Injection whereby standards are set up for the

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material from which the Injection is prepared, i.e., the sterile contents of a sealed container, instead of merely for the solution prepared therefrom which ordinarily is in existence only long enough to be injected into a waiting patient. Another significant revision in respect to preserving sterile solutions is that throughout the general chapter on Injections the term "bactericides" has replaced "bacteriostatics". This substitution will have far reaching implications for the bacteriologist called upon to advise in the preparation of pharmaceuticals.

The growing need for the use of authentic specimens as reference standards is cited and notice taken of the support the Commission has given the programme administered by the World Health Organisation in providing Authentic Chemical Substances from its Centre in Stockholm.

A discussion of what has come to be known among those most concerned as "the thyroid problem" includes notice to the effect that the "study of this complex problem is continuing, and the introduction in this Edition of an assay based on the determination of the total iodine in thyroid combination with a limit test for inorganic iodide should be regarded as a measure subject to review when the results of further work... become available".

While continued recognition is accorded the practice of packaging parenteral solutions in multiple-dose containers, emphasis is placed on the risk associated with such containers arising from their "improper use".

A good measure of the value of a modern pharmacopoeia to its users is the attention given to the general methods by which compliance with the established standards may be determined. A convenient guide to this is the space devoted to the appendices and on this score the B.P. 1963 rates well, for not only is more space devoted to this important section but there is ample evidence that full use has been made of the recent advances in the technology of pharmaceutical analysis. An Appendix dealing with infra-red absorption spectra is new, as is an entire section dealing with chromatographic analysis, nonaqueous titration, and the use of the oxygen flask combustion technique in the preparation of samples for analysis. Among the other innovations is the introduction of directions for sterilising powdered substances, a pharmaceutical procedure of increasing importance in view of the relatively large number of injectable drugs that are too unstable to be distributed in the form of sterile solutions.

The Tests for Sterility are modified in an important way for the antibiotics other than penicillin, the only antibiotic that can be inactivated by procedures that do not affect bacteria that may be present. Thus the other antibiotics are put into solution and passed through a sterile membrane filter disc as a means of "concentrating" any viable micro-organisms to improve the chances of detecting their presence. The disc is then divided into two portions, which are tested for anaerobic and aerobic organisms, respectively.

Giving emphasis to the section on methods, however, should not be allowed to detract from the significance of the additions to and deletions from the list of articles recognised, the monographs for which make up

some 70 per cent of the space of the book. Despite the deletion of a long list of titles for articles that are no longer regarded as deserving of pharmacopœial recognition, the monographs section now occupies 160 pages more than in the preceding edition, mainly because of the many new monographs provided. It is scarcely possible to pick out any individual article or group of articles as having greater significance than others. Pharmacologists will certainly note, however, the return to grace of Diamorphine Hydrochloride, best known as heroin; it was last official in B.P. 1948. This admission is especially noteworthy because of the statutory ban on the distribution of heroin in many parts of the world on account of its pronounced liability to cause addiction.

The British Pharmacopoeia 1963 is the third edition brought out under the direction of the present Secretary of the British Pharmacopoeia Commission since he assumed office in 1951. As an addition to a notable series, it reflects great credit on the Secretary personally and the entire Secretariat; it gives evidence as well of able and unstinting help from the Commission and the many committees appointed to assist it during the revision period.

THE BRITISH PHARMACEUTICAL CODEX, 1963*

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FEW books can exist for a dual purpose and effectively fill both needs; generally either one or both of the aims suffers in such an ambitious undertaking. The British Pharmaceutical Codex is a rare exception to this generalisation, inasmuch as it has a long history of commendable service both as a compilation of highly authoritative and useful therapeutic (actions and uses) information as well as a valuable compendium of recognised and accepted standards and specifications for many pharmaceuticals and dosage forms not included in the corresponding British Pharmacopoeia. The latest revision of the Codex continues in this fine tradition and the reader is pleased to note that further improvements have been made which serve to extend and increase the value and usefulness of the book.

The present volume is the eighth edition in a series dating from 1907, and is intended to become effective, in the United Kingdom on January 1, 1964. Its publication follows by only three and one-half years the appearance of the previous edition, the B.P.C. 1959. The explanation for this accelerated publication programme rests in a mutual desire on the part of the British Pharmacopoeia Commission and the Council of the Pharmaceutical Society of Great Britain to provide a parallel publication schedule for the two books, and so enable them to come into effect on the

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