BOOK REVIEWS

The British Pharmacopoeia 1968*

Reviewed by

HERBERT GRAINGER, F.P.S.

Technical Secretary, European Pharmacopoeia Commission, Council of Europe, Strasburg

The most obvious fact about the B.P. 1968 is that it is fatter than its precedessors, in spite of very strict economy in the white space, which has resulted in an overcrowding of the text on the page. The reason for this is to be seen on pp. xxvii–xxix where the list of 215 new monographs is offset by only about one quarter of its number of deletions. This is the inevitable result of the upsurge of "new" drugs in recent years and presents pharmacopoeia authorities with a difficult task of selection. The B.P. Commission is to be congratulated on having discharged this particular task with distinction, for the B.P. '68 may justly be claimed as the most complete, modern, and highly developed of all present pharmacopoeias.

A note of nostalgia appears on p. xiv where we are informed that the present edition will be the last to be published under the auspices of the General Medical Council which has been responsible for the work since its institution in 1858. Future editions will be the responsibility of whatever organisation is to be established under the auspices of the Medicines Commission provided for in the new Medicines Act of 1968. It is to be hoped that whatever the new system to be evolved, it will continue to recruit the goodwill and the high scientific endeavour of the many experts who have contributed to the successive editions of the B.P. throughout the last 110 years.

Unlike most of the other European pharmacopoeias published in recent years, the B.P. still contains many monographs on pharmaceutical preparations, including some antiquated ones such as sulphur ointment, coal tar solution, compound rhubarb tincture, camphorated tincture of opium, and turpentine liniment.

In the process of rationalization which must inevitably attend the institution of a new regime it may well be that a distinction could be made in future between standards for substances and standard formulae for preparations, with the possible removal of the latter into a separate compendium. This is not to cast doubt, however, on the importance of setting standards for the most widely used pharmaceutical forms, such as tablets, capsules, or injection solutions, of each of those substances which are the subject of monographs. The latter principle has been challenged in many countries, usually by industrial interests, who believe that the formulation of pharmaceutical preparations is now such a complicated and delicate matter that it cannot be adequately treated in the pharmacopoeia. They would prefer to leave the manufacturer free to develop his own formulation which would be divulged (as it must be) only to the authority granting permission for its release onto the market. This view, however, ignores the primary responsibility of the pharmacopoeia authority to protect the user by establishing and publishing objective norms which can be applied at any stage in the chain of distribution of the product.

* *THE BRITISH PHARMACOPOEIA* 1968. Pp. xxxi + 1423. Published for the General Medical Council by The Pharmaceutical Press, 17 Bloomsbury Square, London, W.C.1. £8, post free.

An aspect of quality control of which awareness has increased rapidly in recent years is that of drug availability in the body. The pharmacopoeia has traditionally applied appropriate tests to delayed-action insulin preparations and has a control for the particle size of Griseofulvin but much remains to be done in devising suitable tests in connection with many other formulated products. So far very little has been done in this direction in any pharmacopoeia.

Of particular interest to the reviewer is the reference on page xiv to the relationship between the B.P. Commission and the European Pharmacopoeia Commission. The latter body, set up under the auspices of the Council of Europe (Partial Agreement), unites eight countries in the collaborative revision of pharmacopoeial standards. These will become the official standards in each of the participating countries and will replace the existing monographs in their respective national pharmacopoeias. The first volume of the European Pharmacopoeia is now in the press and its publication early in 1969 will cause some revision in the B.P. monographs concerned. The B.P. Commission, its experts and its staff have played and continue to play a considerable part in the elaboration of the Ph.Eur.

An inevitable development in the B.P. as in other pharmacopoeias is the use of physical and physico-chemical methods to replace classical chemical procedures in the identification or control of purity of drugs. Gas chromatography is introduced for the first time in this edition. Indeed many of the newer substances could not be adequately controlled by the older methods. In consequence it has to be recognized that pharmaceutical analysis is a speciality in its own right, and that it can be carried out satisfactorily only in appropriately equipped laboratories. This fact is not always palatable in some countries where law and tradition still presuppose that the practising pharmacist is directly responsible for the quality of the medicaments he supplies and that he should carry out the analytical procedures necessary to the discharge of that duty. It is clearly uneconomical to equip every pharmacy, or even a substantial proportion of them, with the apparatus and staff necessary for such work. However, the widespread introduction of techniques using thin-layer chromatography both for identification and for the detection of trace impurities should enable laboratories even of modest scope to give more attention to pharmaceutical analysis than has sometimes been the case in the past.

The use of techniques such as chromatography and light absorption has emphasized the need for reference substances of various kinds, such as samples of known purity and known impurities, authentic specimens, and even "pure" impurities. The work of the B.P. Commission in collaboration with the Pharmaceutical Society in making available such substances appears to have gone further than that of the WHO in this field. It is to be hoped that in due course some international agreement can be reached regarding these substances for they are obviously of great importance to all pharmacopoeia authorities.

The new edition continues to include brief statements about the actions and uses of drugs. The value of these statements is not obvious, nor is their presentation uniform. In some cases no statement is made (e.g. Eucalyptus oil) and in others the statement is not very precise, e.g. Eugenol is said to be a "local analgesic used in dentistry". The usual term in dentistry is "obtundent" which avoids confusion with local anaesthetic (? analgesic) solutions injected before extractions, etc. It would be better either to give fuller information, as is done in the B.P.C., or to omit it altogether. As it is not the function of the B.P. to become a handbook of therapeutics, perhaps the latter solution would be best.

This, however, is a small quibble to make concerning such an excellently edited work. The secretariat and the printers have admirably combined to maintain the traditional high quality of presentation. The typography is clear, though small,

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.