PHARMACOPOEIAS AND FORMULARIES

INTERNATIONAL PHARMACOPOEIA FIRST EDITION. SUPPLEMENT*

REVIEWED BY K. R. CAPPER

This Supplement completes the first edition of the International Pharmacopoeia. The completion is marked by the inclusion of a cumulative index to Volumes I and II and the Supplement, and of lists of the monographs in the three books. The 94 monographs in the Supplement include a number for long-established drugs, such as Salicylic Acid, Fluorescein Sodium and Zinc Oxide, as well as many which have achieved official recognition here only in recent editions of the British Pharmacopoeia and its Addenda. Some indeed are not yet in the British Pharmacopoeia, for example, Acetrizoic Acid, Methandriol and Methoxamine Hydrochloride, and, as the B.P. is less than two years old, those who compiled the International Pharmacopoeia have obviously intended to produce a pharmacopoeia which is as up-to-date as practicable. The completed first edition of the International Pharmacopoeia contains well over 500 monographs of which about one-third are for preparation and the full list of monographs is more or less what would be expected in any national pharmacopoeia published towards the end of 1959.

The specifications in the International Pharmacopoeia are not intended to have legal status as such in any country but to serve as a guide to national specifications and in this way will undoubtedly help those countries which have not the potential to set up the complex organisations of expert committees which serve the pharmacopoeia commissions here, in the U.S.A. and elsewhere. It would be equally advantageous if the International Pharmacopoeia could help to achieve standardisation of standards in the national pharmacopoeias and reduce the analytical costs of pharmaceutical manufacturers. With the first edition completed, it is timely to ask how far the first edition of the International Pharmacopoeia has fulfilled either of these functions? The first it has done; any country which insists that is drugs should conform to the specifications of the International Pharmacopoeia will ensure that its medicines will be of high quality. The specifications in the tolerances laid down, and in the details of the limit tests and assays, bear comparison with those in any national pharmacopoeia. If the pharmaceutical industries in any country are not efficient enough to reach the standards of the more advanced countries, they receive no encouragement or compromise in the International Pharmacopoeia. It could, however, be contended that this function could be equally well served, as it has been in the past, by the United States and British Pharmacopoeias on which the Ph.I. monographs are so largely based. There is little to suggest, however, that it will achieve the second aim of an international pharmacopoeia —that of reducing the heterogeneity of national standards. To do so it would need to show some advance on the specifications in these. The lengthy list of experts given in the preface is impressive but it is not clearly stated which of these actually contributed towards the preparation of the Supplement monographs. There is some reason to believe that the work has been principally

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done by the secretaries of pharmacopoeia commissions and other experts on pharmacopoeia-making. That this should have been so is reasonable enough. The result, however, has been that most of the 500 or so monographs reproduce, with minor differences, those of one or other of the major national pharmacopoeias distributed in a manner which admirably couples impartiality with a nice recognition of national prestige. There is, however, little evidence of an original and authoritative approach in the individual methods for tests and assays. A minor example of a major weakness is shown in the inclusion of a limit test of lead (as in the B.P.) in some monographs and for heavy metals (as in the U.S.P.) in others—8 drugs must comply with the first and 9 with the latter, 2 with both. The Expert Advisory Panel must rely heavily on the key persons in the principal pharmacopoeia commissions as these persons have experience in producing this sort of book and they can best give a consensus of national opinion. Nevertheless, unless their efforts are supplemented by those with experience in applying the specifications in the laboratory, the International Pharmacopoeia will never be anything more than an admirable example of national compromise with an international label. There are listed in the preface those with such experience but there are no pharmaceutical analysts from Great Britain although there are several of international reputation who might have been asked to serve. Now that the huge task of preparing the first edition is complete, special attention might be given to this aspect and especially to standardising methods.

The section of the Supplement which is of greatest general interest is that which contains the Appendices. Two of these are especially useful. Appendix 16 contains a full list of International Biological Standards and reference samples, a list which is remarkably comprehensive and includes Standards for veterinary as well as human preparations. References to papers relevant to the standards are contained in the recently published 12th Report of the Expert Committee on Biological Standardisation (W.H.O. Technical Report Series, No. 172). It is regrettable that so many of these references are to unpublished working documents of the W.H.O. Expert Committee on Biological Standardisation. Reference substances for assays depending on spectrophotometric analysis and other physico-chemical methods are badly needed to make this procedure a reliable method of assay; Appendix 17 contains a modest, but promising, list of 8 authentic chemical substances for this purpose. Appendix 7 gives graphs for preparing isotonic solutions similar to those in the Danish Pharmacopoeia and equally useful. The table of doses for children given in other pharmacopoeias but not in the B.P. will also be welcomed. The Supplement completes an International Pharmacopoeia which, if no better than the best national pharmacopoeias, is little, if at all, worse. That this should be so is remarkable in the circumstances and reflects great credit on those concerned.