Attitude towards Reforms

It has been urged, too, in some quarters that the Council might well surrender its right of inspection of examinations and visitation of schools and be guided by the verdict of the University Grants Committee, which inspects schools thoroughly every five years. But the authority of the University Grants Committee does not extend beyond university courses and examinations, and it would probably not wish for any addition to its labour. Eire, in any event, is not within its jurisdiction.

It is extremely unlikely, therefore, that agreement could have been reached on any reform, because there is no doubt that controversy about the right type of training still persists and in some quarters is bitter. There are those who believe that the medical student should be mainly taught the techniques of a practical art, while others hold that his training should be shaped by the academic ideal of a sound training in basic and clinical science in the hope that he will emerge with a critical mind which enables him to take advantage of the experience that will come to him in practice. Reasonable people agree that both types of training are necessary, though opinions differ over the emphasis to be accorded to each of them. The General Medical Council was wise not to enter any of the fields of conflict. It realized that many of the provincial medical schools had been absorbed by civic universities and that these young and vigorous institutions, jealous of their autonomy and independence, were unlikely to accept readily precise directions on the curricula of their faculties and that the idea of reasonable diversity in educational matters would be sooner achieved if it left the responsibility of experiment to the individual schools and was content to maintain an adequate minimum standard which was the duty imposed on it by Act of Parliament.

The liberal character of the current Recommendations which set the schools almost entirely free to plan their own curricula is not due to an abdication of responsibility on the part of the Council; the change is a sensible recognition of a new situation. The medical schools are now mature, and in Great Britain and Northern Ireland they are free from the poverty that crippled them less than twenty years ago.

The compulsory pre-registration year of hospital practice under supervision, the establishment of the consultant service, and the fact that a period of assistantship almost invariably precedes independent general practice make it extremely unlikely that the public will suffer at the hands of an insufficiently trained doctor. In such circumstances the Council felt able to give more freedom to the schools.

The great achievements of the General Medical Council in education belong to the first fifty years of its existence; its influence was paramount in raising medical practice from the status of a dubious trade to that of a learned profession. The following fifty years were a period of consolidation rather than activity. The Council was content to wait on the development of the schools and finally to place on them the responsibility for experiment and further advance. That policy, in view of all the difficulties, the future will probably justify.

Work Overseas

The educational work of the Council is not restricted to these islands: in the immediate past it has done as much for medical education in the Colonies as its predecessors accomplished in England in the early years. No one who has visited medical schools in the Colonies or in countries like India, which have since become independent, can have failed to notice the immense prestige of the Council overseas. To obtain recognition of their training and degrees as qualifying for admission to the English Register has been and still is the ambition of many of them.

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**THE HISTORY AND DEVELOPMENT
OF THE "BRITISH PHARMACOPOEIA"**

BY

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Descriptive catalogues of drugs claimed to be useful in the practice of medicine have been compiled since the night of time, and a bibliography of them published in Germany in 1784 includes such classic names as Celsus, Pliny, Galen, Dioscorides, Avicenna, and Paracelsus. The first work of this nature, however, with the imprint of authority was probably the *Dispensatorium Pharmacorum Omnium* issued in 1546 with the sanction of the Senate of Nuremberg. The title "pharmacopoeia" is said to have been applied for the first time to a book published in Basle in 1561.

In England the importance of ensuring the purity of drugs was officially recognized as long ago as 1518. In that year the Letters Patent constituting the College of Physicians granted by Henry VIII provided for the election of four persons appointed by the College to have the supervision and scrutiny of every kind of medicine and the prescription thereof by physicians practising within a radius of seven miles of the City of London. A subsequent Act of 1540 gave such persons power to enter the premises of all apothecaries and to destroy any defective drugs found there. The first *London Pharmacopoeia*, dedicated to James I, was published by the College in 1618, a century after its foundation. It included no fewer than 1,028 drugs and 932 compounds, often of a bizarre and even revolting character. Subsequent editions appeared regularly, the tenth and last *London Pharmacopoeia* being published in 1851. From the beginning the book had authoritative countenance and proceedings were authorized against those compounding medicines in any other form than therein directed.

In Scotland the President and Censors of the College of Physicians of Edinburgh, which received its Charter from Charles II in 1681, were likewise empowered to inspect drugs and medicaments offered for sale within the city and suburbs and to throw into the street or destroy those found to be insufficient or corrupt. Similar activities were undertaken in Glasgow by the Faculty of Physicians and Surgeons. The Edinburgh College published its first *Pharmacopoeia*, dedicated to William III, in 1699, and subsequent editions were issued at intervals till 1841, when the fourteenth and last *Edinburgh Pharmacopoeia* appeared.

The Censors of the College of Physicians in Ireland, founded by Charles II in 1667 and reincorporated by William and Mary in 1692, were similarly ordered to inspect medicines within the City of Dublin and its environs and to destroy those which were defective. It was not, however, till 1807 that the first *Dublin Pharmacopoeia* appeared, and a revised edition was published in 1826. The third and last *Dublin Pharmacopoeia* was issued in 1850.

The First British Pharmacopoeia

The inconvenience resulting from the existence of three different pharmacopoeias in the United Kingdom and Ireland was considerable, and when the Medical Act of 1858 established the General Council of Medical Education and Registration it enjoined the Council among other things to publish a single pharmacopoeia to supersede those of London, Edinburgh, and Dublin. Immediately after its constitution, therefore, a committee of the Council was set up to take the necessary steps for the preparation of a *British Pharmacopoeia*. This committee consisted of members of the Council, and was divided into three subcommittees, meeting respectively in London, Edinburgh, and Dublin. The task of reducing to one standard the processes and descriptions of three pharmacopoeias and of reconciling the varying pharmaceutical customs and prescribing idiosyncrasies of the three countries must have been formidable, and, perhaps not surprisingly, the work which was published in 1864 was found to have many imperfections. Thus more than half of the 28,000 copies published were destroyed and a loss of £1,206 was incurred on the first edition. The Council issued a second and more successful pharmacopoeia in 1867, a third in 1885, a fourth in 1898 (with an Indian edition in 1901), and a fifth in 1914.

The preparation of each volume was undertaken by a committee of members of the Council. It could only be by a fortunate coincidence that there might be on the Council from time to time men who possessed the specialized knowledge requisite for the compilation of such a work, for members of the Council are selected not with a view to their fitness and capacity to prepare a pharmacopoeia, but rather because of their general ability, their administrative gifts, and their professional standing. Thus it was necessary for the committee in preparing each new pharmacopoeia, especially the later editions, to make extensive use of outside technical assistance by invoking the aid of pharmacists and other experts. Early in the present century it became clear that these external authorities were dissatisfied with the status accorded to them in relation to the work. They argued that if their co-operation was indispensable, as it was conceded to be, their position should be recognized by giving them a right of participation in the work not merely as consultants but as colleagues.

The difficulty was resolved by a report prepared in 1928 by a subcommittee of the Committee on Civil Research under the chairmanship of the Right Hon. H. P. Macmillan—afterwards Lord Macmillan. As the result of its recommendations a British Pharmacopoeia Commission was established with a permanent secretary and other officers employed by the Council. The Commission consists of up to a dozen medical and non-medical experts appointed from time to time by the Council, acting in accordance with recommendations made by a selection committee, four members of which are nominated by the Council, two by the Medical Research Council, and one each by the Pharmaceutical Society of Great Britain, the Pharmaceutical Society of Ireland, and the Pharmaceutical Society of Northern Ireland. The Commission, which maintains a laboratory, is financially self-supporting through the sales of the *Pharmacopoeia*.

Thus the Council accepts responsibility for the work of the Commission which it calls into being. On questions of policy the Council retains the power not only to give general directions to the Commission but to refer back to it for reconsideration any matters it may deem proper. This does not involve any lessening of the Commission's responsibility on the technical side, while the position of the Council resembles that of many other eminent bodies which rely upon the work of expert committees and are prepared to accept responsibility for it. Under these arrangements the Council published the 1932 *Pharmacopoeia*.

Intervals Between Editions

It was originally intended to publish the seventh edition not later than 1942, but wartime conditions caused its post-

ponement till 1948. The progress of pharmaceutical and therapeutic knowledge then became so rapid that the Council, on the advice of its Commission, resolved that in future the normal interval between the publication of editions should be reduced to five years, with an Addendum some two and a half years after the issue of each volume. There had, of course, been many Addenda to previous editions of the *Pharmacopoeia*.

The preparation, publication, printing, and selling of successive editions of the *Pharmacopoeia* were provided for by the Medical Act of 1858 and the Medical Council Act of 1862. These statutory provisions were amended by the Medical Act of 1950, which, among many other things, contained a section that made two notable innovations in regard to the *British Pharmacopoeia*. The Medical Act of 1858 defined the *Pharmacopoeia* as a book "containing a list of medicines and compounds, and the manner of preparing them, together with the true weights and measures by which they are to be prepared and mixed, and containing such other matter and things related thereto as the Council shall think fit." This definition was appropriate to the preponderance of galenical preparations contained in the earlier editions; these were controlled largely by their formulae and methods of preparation rather than by a series of tests and assays.

The Act of 1950 describes the *Pharmacopoeia* as containing "such descriptions of and standards for, and such notes and other matter relating to, medicines, preparations, materials and articles used in the practice of medicine, surgery or midwifery as the Council may direct." Thus the permitted scope of the *Pharmacopoeia* was at once enlarged both in the range of materials which may be the subject of monographs and in the variety of information which may be included. The replacement of "medicines and compounds" by "medicines, preparations, materials and articles" makes it clear that diagnostic agents, surgical dressings, ligatures, haemostatics, and the like are all within the authorized scope of the *Pharmacopoeia*. The elaboration of analytical procedures for controlling the purity of drugs has caused the appendices of the *Pharmacopoeia* to be greatly extended so as to provide details of chemical, physical, and biological tests.

The second innovation provided by the Medical Act facilitates the introduction of a new edition. Formerly, the General Medical Council had no authority to publish a new edition in advance of the date on which it came into effect, and the best arrangements which could be made for interested parties to consult advance copies of a new *Pharmacopoeia* still caused great inconvenience, especially to those working at a distance from the Council's office. The Council is now authorized to publish the book in advance of the date on which it is to have effect. Thus, the *British Pharmacopoeias* of 1953 and 1958 did not become official until a period of six months had elapsed from the date of their publication.

Authoritative Standard

The observance of the *London Pharmacopoeia* in the making and compounding of medicines was enjoined by the Order-in-Council of 1851, but there has been no legislation dealing generally with the legal status of the *British Pharmacopoeia*. There are references to it in a number of enactments which confer statutory recognition for certain purposes, as in the Pharmacy and Medicines Act and the Pharmacy and Poisons Act. It is accepted as providing standards for certain drugs by the Drug Tariff issued in accordance with the National Health Service regulations. The substantial legal protection provided for the public to ensure the purity of drugs is found in the provisions of the Food and Drugs Act, 1955, as in the earlier Act of 1938. The policy there expressed does not refer by name to any particular standards, but in general terms requires that "if a person sells to the prejudice of the purchaser any food or drug which is not of the nature, or not of the substance, or not of the quality, of the food or drug demanded by the purchaser, he shall . . . be guilty of an offence."

In this situation a bench of magistrates must accept some authority, and over the years the *British Pharmacopoeia* has been recognized as providing the presumptive standard when a purchaser demands a drug described therein. Decisions made by the High Court from time to time justify the acceptance of certain principles in relation to pharmacopoeial drugs. The sale on demand of such a drug which does not comply with the requirements laid down in the *British Pharmacopoeia* provides at least *prima facie* evidence that the sample is not of the nature, substance, and quality demanded. It is not necessary for the purchaser to refer specifically to the *Pharmacopoeia*; the use of the official title or subsidiary title is sufficient to establish that the article demanded was that specified in the book.

Drugs Included in the "B.P."

The selection of drugs to be included in the *Pharmacopoeia* is decided principally on clinical and pharmacological grounds, but pharmaceutical knowledge is a factor in deciding on the form in which drugs are to be presented for use. In selecting the drugs for inclusion the endeavour is made to produce a book that will represent the latest achievements of medical science while at the same time recognizing many older forms of medication of proved value which are still in frequent use and still require control. Thus in the 1958 *Pharmacopoeia* monographs on new drugs such as hyaluronidase, hydrocortisone, radioactive isotopes, noradrenaline, reserpine, and the tetracyclines rub shoulders with 150 respected survivors from the first *British Pharmacopoeia* of 1864, such as atropine, digitalis leaf, ferrous sulphate, opium, magnesium carbonate, and senna.

Before determining the articles to be included in the book a large number of medical and pharmaceutical authorities are consulted. The proposals are submitted for comment to medical and pharmaceutical bodies and individual experts throughout the British Commonwealth as well as to the special committees appointed in the Dominions to deal with pharmacopoeial revision, and decisions are taken by the Commission after consideration of the recommendations received. The wide range of information contained in the book makes it necessary for the Commission to appoint many committees of experts, each of which is presided over by a member of the Commission, to elaborate the specifications required for the monographs and appendices.

In addition the Therapeutic Substances Act authority is consulted on all matters which come under the control of its regulations. There is a constant exchange of information with the Committee of Revision of the *United States Pharmacopoeia*, and the Commission is kept informed of the work of the expert committees of the World Health Organization and the *International Pharmacopoeia*. Consultation with the Revision Committee of the *British Pharmaceutical Codex* is maintained with the object of keeping the two works in harmony.

Nomenclature

The 1953 edition of the *Pharmacopoeia* will be remembered for the introduction of English instead of Latin titles. It would, for example, have taxed the ingenuity of the most erudite scholar of the humanities to have rendered into tolerable Latin "Concentrated Human Red Blood Corpuscles," and the practice of changing the last syllables in such English titles as acetomenaphthone and sulphadimidine to acetomenaphthonum and sulphadimidina had become an act of supererogation.

A further activity arising from pharmacopoeial nomenclature was the recognition by the Council, on the recommendation of the Commission, of "approved names" for certain drugs. This activity became necessary early in the last war through the disappearance of certain German drugs known only by their trade-mark names and the consequent need for official non-proprietary names for their British counterparts. Thus mepacrine was provided as the approved name for the drug previously known as "atebrin." After

the war the great developments of the pharmaceutical industry led to the introduction of vast numbers of new drugs issued under various proprietary names. The unsatisfactory position created by the issue of the same drug under a variety of such names by different manufacturers and the restrictions put upon their use is generally acknowledged and has been the subject of frequent comment. The intention is to provide non-proprietary names which can be used by any manufacturer, prescriber, or pharmacist, and, if the drug is eventually described in the *British Pharmacopoeia*, the approved name is used as the official title. A list of these approved names, showing also the proprietary names, some of them trade-marks, is published by the Council from time to time. A pamphlet containing these lists is included in each copy of the *Pharmacopoeia*, and numbers of them are sent to hospitals and medical schools.

The Metric System

The gradual displacement of the Imperial System of Weights and Measures by the metric system has proceeded throughout the history of the *Pharmacopoeia*. The first edition referred only to the Imperial system. In the second edition of 1867, solutions for volumetric analysis were defined in terms of British Weights and Measures and Metrical Weights and Measures. In 1898 the metric system entirely replaced the Imperial in all analytical procedures, and the formulae for preparations were expressed in both systems. In the 1914 edition the statements on doses were given in both systems and the formulae in the metric system only. In the 1953 edition the metric system alone was used throughout the appendices and monographs except in the expression of doses of substances commonly prescribed in the Imperial system. For these latter the Imperial dose was stated in parenthesis after the metric dose. All the doses of the new drugs introduced into the 1958 edition are given in the metric system only, for these drugs have almost invariably been introduced into medicine and used in dosage terms based on the metric notation, and nothing would be gained by adding an equivalent Imperial dose. The Council has approved the recommendation of its Commission that in the 1963 *Pharmacopoeia* all reference to the Imperial system should be entirely abolished.

A Misconception

Some of the criticism of the *British Pharmacopoeia* proceeds from a misconception of the purpose of the work. It is not designed to be a manual of therapeutics to be consulted by the doctor in his daily practice. For him its function is that of a guarantee that when he prescribes a drug mentioned in the *B.P.* he can rely on his patient obtaining an article of the quality and character therein defined. To the dispenser, on the other hand, it is actually a manual of practice. He must dispense according to the standard of the *B.P.* any medicament contained in it which is mentioned in the prescription handed to him.

The long intervals which in the past sometimes separated the publication of one edition from another—particularly the time which, owing to the war, elapsed between the editions of 1932 and 1948—sometimes resulted in the *British Pharmacopoeia* being derided as an old-fashioned compendium of drugs which had had their day and been found wanting. Now that the *Pharmacopoeia* is produced every five years with an Addendum two and a half years after each publication this criticism no longer applies. The 1958 *Pharmacopoeia* is a very modern scientific work, and might indeed be criticized more for running too far ahead of medical practice than for lagging excessively behind it.

The Next Edition

Like the labours of Sisyphus, the production of successive editions proceeds without interruption, and when the Commission of 1953-8 demitted office on September 1—the date on which the 1958 *British Pharmacopoeia* became official—a newly appointed Commission immediately took up the task of preparing the 1963 edition.