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Editorial

The definition and maintenance of objective standards for the quality of drugs, auxiliary substances and formulated medicines is of major strategic importance in underpinning the quality of health care services throughout the world. In this respect national Pharmacopoeial Authorities and the European Pharmacopoeia, together with Governmental Regulatory Agencies, play a key rôle in establishing relevant and discriminating standards for drugs and drug formulations, and in validating their application at all levels of the manufacturing and distribution process. Consultation between the national and international authorities, the pharmaceutical industry and health care service professionals is a very well established process in relation to specific drugs or issues of topical importance. However, it is rare for a national Pharmacopoeial Authority to issue a general policy document detailing its mission statement in the health care field. Thus the recent document on "The British Pharmacopoeia into the 1990s" published by the British Pharmacopoeia Commission is a welcome contribution to the international debate on the contemporary rôle of a national pharmacopoeia in the control of medicines, and the prospects for development in the future.

The BPC document is all the more interesting for its being the first such major policy statement since the British Pharmacopoeia was established in 1864. The Commission defines its mission to provide objective and public standards of quality for medicines and describes how this mission is realised through publication of the British Pharmacopoeia and participation in the work of the European Pharmacopoeia. The relationship between product licensing, medicines inspection and the Pharmacopoeia is explored and the Pharmacopoeia's contribution to the overall system of control of medicines is explained.

Since the UK Medicines Act was published in 1968, the statutory process for assuring the quality of medicines in the UK has been based on three interdependent systems — the confidential licensing procedures which are supported by the work of the Medicines Inspectorate, together with the public specifications of the BP. In common with other national Pharmacopoeias the BP contributes to this process by providing standards that are objective and applicable in principle to the products of all manufacturers. They are published and readily available to all who need to use them, whether suppliers, purchasers, inspectors, medicines regulators or independent control laboratories. Users participate in the development of pharmacopoeial standards and the Pharmacopoeia is responsive to their proposals for new or revised specifications.

Public recognition of the 'BP' hallmark contributes to consumer confidence in the quality of medicines in the UK and many other countries. As a country with a strong national pharmacopoeia, the UK continues to be a major influence in shaping European policies for the control of medicines. European Pharmacopoeia monographs are the legal standards in 20 European states and the British Pharmacopoeia Commission, its advisers and staff participate actively at all stages in the work of the European Pharmacopoeia. An effective national pharmacopoeial organisation provides the UK with a direct and influential channel of communication to the European Pharmacopoeia Commission itself. The close cooperation that exists between British manufacturers and the staff of the British Pharmacopoeia Commission is an important element in this process.

The Commission states in unequivocal terms that "it has been, is and will continue to be a major influence in shaping European policies for the control of medicines". The next few years will see a high degree of integration in the way Europe manages its control of medicines. A major rôle of the British Pharmacopoeia Commission will be to assist the European Pharmacopoeia to meet the various needs of those who invent, develop and manufacture, those who license, those who inspect and those who use medicines. To achieve these ends, a strong national competence will be maintained so that influential contributions can continue to be made at all

levels of the European Pharmacopoeia Commission's work.

As Editors of this international journal, we recognise the important rôle that the publication of high quality analytical research on drugs and formulated medicines in a primary reference journal plays in the eventual development of high quality standards in pharmacopoeias. We welcome this document from the British Pharmacopoeia Commission as a timely and forward-looking mission statement, that is bound to contribute to improved understanding of the function fulfilled by one of the oldest and most well established pharmacopoeial authorities in the world. We trust that the scientific community will welcome this document as an informed and informative description of one of the vital links in the process of ensuring the safety and efficacy of medicines thoughout the world.

Anthony F. Fell
Christopher M. Riley
Derek H. Calam