

Points of View

Cooperation within the Council for Mutual Economic Assistance (CMEA)

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The Council for Mutual Economic Assistance, as originally established in 1949, was the embodiment of a contract among the participating Member States to promote economic and social development through integration of industrial resources and cooperation in science and technology. The predominantly European structure of the Council conferred upon it by the six original signatories — Bulgaria, Czechoslovakia, Hungary, Poland, Rumania and the USSR — was subsequently modified by the accession of Mongolia, Cuba and Vietnam in addition to the German Democratic Republic. Since its inception, the permanent Secretariat has been located in Moscow, but institutions in other Member Countries have subsequently been designated to coordinate specialized programmes.

As elsewhere, a need for a unified system to assure the quality, efficacy and safety of medicinal products became evident in the early 1960s. Acceptance of common norms and standards based upon secure technical criteria was perceived both as a safeguard to patients and as a means of fostering cooperation in the manufacture and supply of active drug substances and finished products destined to circulate within the participating countries. With this in view, the National Institute of Drugs of the German Democratic Republic was designated in 1965 to

coordinate a technical programme directed to the development of common quality specifications.

This unification was initially achieved through the *Compendium Medicamentorum*, an official publication of the CMEA. This is not a pharmacopoeia in the generally-accepted sense, but rather a set of requirements which manufacturers and national regulatory authorities are expected to satisfy with respect to medicinal products exported to other Member Countries. It contains basic norms and testing methods, directions for labelling, a register of permitted reagents and auxiliary substances. It remains extant as a publication, but plans are now in hand to produce a formal CMEA pharmacopoeia.

Active collaboration between the respective national public health authorities was significantly intensified in 1975 when high priority was accorded to upgrading technology applied within health care institutions throughout the participating countries. It was recognized from the outset that this objective created a need not only to review health-care policies but to evaluate the cost/benefit of therapeutic modalities, including drugs and diagnostic agents. At the same time, it was recognized that innovation could not be allowed to compromise basic priorities. To this end, Member Countries have long been involved in collaborative efforts to ensure that the pharmaceutical industry continues to meet anticipated demand for widely used drugs.

To promote research-based activities and to facilitate joint development projects, a series of general guidelines have already been formulated, and a system of mutual recognition of preclinical testing programmes and clinical trials has been established. However, the process of harmonization is perceived as open-ended. A focus for coordinating the necessary technical activities was consequently created in 1981 within the Hungarian National Institute of Pharmacy. An initial consolidated listing of requirements for the conduct and documentation of toxicological tests and clinical trials was issued by that centre in 1987. A second volume, now in press, will detail methods for identifying compounds with specific pharmacological activity and for testing them during both the preclinical and clinical phases of drug development. Soviet research institutions have made a considerable contribution to this

project, which holds particular importance since it has resulted in agreement among the collaborating countries on the data required to support applications for the registration of new drugs, and thus avert unnecessary duplication of effort.

Close attention is now being accorded to the development of vaccines and other immunological agents. To this end, the CMEA has appointed an *ad hoc* Group of Experts to elaborate criteria for their assessment in the light of WHO recommendations and to establish mutually acceptable registration requirements. In undertaking this work, the Council will have access to relevant data contained within manufacturers' applications and the registration records of the competent national authorities.

Implicit in the need for innovation is a complementary need for sustained postmarketing evaluation of drugs, both to detect unanticipated adverse effects and to review their usefulness on the evidence of their performance in routine practice. A system of spontaneous adverse drug reaction monitoring was first introduced in Czechoslovakia in 1971, and this has subsequently served as the basis for creating a

common system. This is coordinated within the State Institute for Drug control in Prague where a related information centre was established in 1986. Studies of drug usage are also undertaken at national or regional level:

- to identify prevailing patterns of prescribing within each level of the health care systems;
- to estimate drug needs in relation to local morbidity patterns;
- to assist in planning the provision of health services; and
- to detect possible misuse or under-use of specific products or groups of products.

This work reflects the importance that is attached to knowledge of how drugs are currently used and what they achieve in different medical settings. It is seen as a vital prerequisite to development of educational programmes, to satisfying informational needs and to planning the research-based activities needed to develop the drugs of the future.