

# General Policy Topics

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## Drug control in small countries

The recent evolution of drug control in highly-developed countries was set on course by the thalidomide catastrophe of the early 1960s which imposed an onerous commitment on regulatory authorities to prevent the admission of unacceptably hazardous new drugs to the market. Primacy is still widely accorded in these countries to the assessment of newly-developed drugs and to complex technical considerations regarding their potential safety in man on the basis of experimental data generated largely in animal models. With the passage of time, the information obtained from these models, although of value, has been acknowledged as fallible and a need has been perceived for routine systematic post-marketing surveillance of newly-registered products and for the development of epidemiologically-based approaches to the monitoring process. Orientations have changed, but the technical basis of new drug assessment remains a complex, multidisciplinary process.

This image provides a commonly-projected but singularly incomplete picture of the broader process of drug control, and its sophistication has created a disincentive for many small developing countries to become engaged in the complementary administrative aspects of the regulatory process. New drug assessment holds scant relevance to countries that, because of their lack of market potential, need actively to commission medical supplies from foreign manufacturers. For them, the challenge is to set into place a system of product licensing that provides a sound basis for rationalizing their procurement policies and for assuring the quality and safety of the products they select.

The importance of establishing guiding principles for national drug regulatory authorities in small countries was emphasized in 1985 during the Nairobi Conference on the Rational Use of Drugs, and a consultation recently convened by WHO, in which representatives from six such countries participated, has provided important insights both into the problems at issue and into the existing

infrastructure of drug control in the developing world. Although these countries varied strikingly in population, location, geographic characteristics, demography and affluence, striking similarities were evident in the staffing structures of their regulatory authorities. On average, three full-time pharmacists with a similar number of supporting staff were engaged in drug registration and, in most cases, these were supported by a small advisory committee of independent doctors and pharmacists convened on either a regular or *ad hoc* basis. In one case this group also served as the National Formulary Committee. In no instance were more than two pharmacists employed full-time within the drug inspectorate where reliance was often placed on auxiliary personnel and part-time support, sometimes offered on a voluntary basis. One authority possessed laboratory facilities for full pharmacopoeial analyses; others had none and, of these, only one had ready access to a regional quality control laboratory. None had developed a structured system for post-marketing surveillance of registered drugs.

It is to this reality that guiding principles must be addressed if they are to hold practical significance. It would be a mistake, however, to view the challenge in a negative light. Developing countries are inevitably severely restricted — as are many more affluent nations — in their capacity to engage in a systematic approach to quality control involving either inspection or pharmacopoeial analysis. They are bound to remain largely reliant, in matters of quality assurance, on rigorous implementation of the WHO Certification Scheme, although they might consider, with advantage, the wider application of simple chemical identification tests outside the laboratory to detect fraudulent products and gross degradation of supplies in the distribution chain. However, limitations in resources and manpower are less critical to the creation of a sound administrative structure. A number of small regulatory authorities have already undertaken a full inventory of the medicinal products circulating in their domestic markets and of the responsible importers, wholesalers and manufacturers. In so doing, they have taken the first essential step in the creation of the licensing system that must be in place to provide an effective basis for regulatory action.

Their immediate requirements are twofold. Firstly, they need to organize this information in a computerized data-base that will provide for its systematic and selective retrieval. Secondly, they need to assure their access to the existing international communications network developed for drug regulators under the aegis of WHO.

Given little more than strong motivation and resolution of purpose, these needs can surely be met. Much information on national drug regulatory decisions is now disseminated month by month by WHO to all ministries of health, and the biennial International Conferences of Drug Regulatory Authorities have done much to dispel feelings of isolation among regulators from smaller countries.

Equally significantly, recent developments in microcircuitry and commercialized computer software packages have created the possibility of organizing and operating a basic, yet effective, national drug licensing system from a standard desktop computer. Over the years, inconsistencies in the format of product-specific information required by different regulatory authorities have proved irritating and burdensome to regulators and regulated alike. Much advantage and cost-saving will accrue both to regulatory authorities and pharmaceutical companies if early initiatives are taken to promote international harmonization in the design and content of the many data-bases that will inevitably materialize in the near future to support the licensing process.

## The Rational Use of Drugs

Report of the Conference of Experts,  
Nairobi, 25–29 November 1985

As a unique record of the views and interests of all parties concerned in the world drug situation, this book serves as a key source of guidance in the development and planning of actions necessary to ensure that drugs are used more rationally throughout the world.

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