

## Recent Publications

---

### The case for self-sufficiency in drug control

Over 15 years have now passed since WHO published its first model list of essential drugs. The initiative was unanimously commended at the time by its Member States as providing a compelling and practicable basis for rationalizing drug markets throughout the developing world. However, it was cautiously acknowledged without commitment by an international industry loathe to countenance a radical constraint to the freedom of market forces.

With the passage of time, views have mellowed and the representative bodies of that industry have become increasingly supportive of the essential drugs concept both as a means of extending health coverage in developing countries and in applying the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.

None the less, accusations remain unabated that standards of promotion by leading multinational companies frequently offend not only the truth but also basic public health interests. Distressing advertising copy is sometimes paraded to give credibility to the charges. But to what extent are these aberrations representative of prevailing standards at large in developing countries?

The message of Dr Milton Silverman and his colleagues merits particular respect. First-hand observation in a varied but representative group of developing countries has led Silverman to conclude that, all too often, improvement in drug distribution over the past few years has been more than offset by poverty and growth of populations; and that, wherever multinational companies have raised their standards, locally-based companies have emerged to exploit the situation. A decade or so after perceived dangers associated with drugs such as clioquinol, dipyrone, and phenylbutazone aroused reactive regulatory action in many industrialized countries, locally manufactured versions apparently now abound in the developing world without so much as a warning of potentially serious adverse effects.

These are accusations of fundamental importance. If they withstand the test of independent examination, they will demonstrate a reality that much consumer opinion in industrialized countries has long been reticent to accept: countries vulnerable to abuse of their pharmaceutical markets cannot be effectively helped solely by applying exemplary pressures and boycotts on the far-distant head office of multinational companies. The countries at risk must be helped to help themselves through the development of effective pharmacy services and the creation of business-like national drug regulatory systems.

Where there are immediate and evident shortfalls in the availability of vital life-saving medicines, the call to build up national regulatory infrastructures takes second place. In the face of the widespread circulation of substandard, time-expired and fraudulently manufactured products, a measure of quality simply has to be assured if public confidence in national health care systems is not to become dangerously eroded.

The evidence that Dr Silverman now produces and the conclusions that he draws lend credence to WHO's efforts over the past years to establish practicable guiding principles for drug regulation in developing countries. Only some 25 years have passed since drug regulation in its current form started to evolve within Europe. Much was achieved in the early days with no more than a handful of motivated professionals. With the development of efficient international systems of information exchange, of national certification procedures to establish the authenticity and regulatory status of exported products, and the creation of simplified computerized information storage and retrieval systems to serve the registration process, the task has been greatly facilitated.

Much of value could stem from Silverman's analyses if he is found to be persuasive in identifying the principal targets for attention. The hope must be that he will sensitize and mobilize consumer opinion in general to the need for assisting all countries toward self-sufficiency in their responsibilities for effective drug control.

Silverman, M., Lydecker, M., Lee, P. *Bad medicine: the prescription drug industry in the Third World*. Stanford University Press, Stanford, 1992.