

Foreword by Howard A. Zucker

The past 25 years have witnessed major challenges and successes in the field of public health. Carefully planned and implemented measures for prevention and control have shown their worth in battling formidable infectious scourges: smallpox was eradicated in 1979, and the public health menace measles has been contained. New drugs have been developed for HIV infection, dramatically improving the prognosis of those who receive antiretroviral therapy. Even with new menaces, such as avian influenza, and setbacks to such programs as polio eradication, the control of communicable diseases is technically feasible.

What is technically possible, however, has not always been accessible by developing countries. Indeed, access to appropriate treatments for diseases and conditions that disproportionately affect developing countries is still a big stumbling block. Part of the problem stems from inadequate health-services coverage: one-third of the world's population lacks regular access to essential modern medicine (up to one-half, in certain parts of Africa and Asia). Direct financial constraints contribute to the problem. Drug discovery and development is a complex, lengthy, and costly process. As recently reviewed in the World Health Organization Report of the Commission on Intellectual Property Rights, Innovation and Public Health (see pages 17 and 76 of that report*), even moderate estimates of the cost of R&D for some drugs put the total between US\$115 million and US\$240 million.

Socio-cultural inequalities also have a profound affect on distribution. The majority of potential patients live in the poorer parts of the world, whereas the majority of drug and vaccine producers—and purchasers—are found in affluent countries. Although developing countries have more than 80 percent of the world's population, they account for only about 10% of drug sales. Major pharmaceutical producers—however great their desire to benefit all—are answerable to market forces and to the wishes of shareholders.

For health products, both demand and supply are out of balance. Many public-health-policy experts have pointed to the concept of IP (intellectual property) rights—the protection of intellectual and financial investments in new drugs and vaccines—as contributing to this imbalance and inequity. As part of the ongoing international debate about the wider aspects of the relationship between IP rights, innovation, and public health, the World Health Assembly under the auspices of the World Health Organization decided to establish an independent Commission to analyze the issue. The Commission's report, released in

Zucker HA. 2007. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

© 2007. HA Zucker. *Sharing the Art of IP Management*: Photocopying and distribution through the Internet for noncommercial purposes is permitted and encouraged.

2006, states that governments around the world have recognized moral and legal issues with respect to ensuring general access to existing drugs (see pages 8 and 9 of that report). This access is essential for sustaining government efforts in developing countries and elsewhere to control disease.

As a follow-up to the Commission's report, a working group comprising government officials and other key stakeholders in public health, innovation, and intellectual property is developing a global strategy and plan of action. The goal is to secure an enhanced and sustainable basis for need-driven health research and development aimed at curing or treating diseases that disproportionately affect developing countries. The strategy being discussed includes "*making intellectual property work for health*" as one of three major challenges. Among eight elements of the proposed plan of action for implementing the strategy is the management of intellectual property, including such aspects as legislation, incentives, documentation, training, and regulation.

In deliberations of the intergovernmental working group, Member States have identified IP management as a key element of progress in the fight against diseases, an element that poses complex and sensitive problems in the realms of ethics, economics, and health policies. This *Handbook of Best Practices* is both timely and highly relevant. It is hoped that the *Handbook* will help build capacity in decision making at the national level by assisting academics, researchers, and policy-makers—especially in the developing world—to clarify many of the issues that currently influence the relationship between generalized access to drugs and the protection of IP rights.

*March 2007
Geneva, Switzerland*

* <http://www.who.int/intellectualproperty/report/en/index.html>

HOWARD A. ZUCKER, *Assistant Director-General, Health Technology and Pharmaceuticals, Representative of the Director-General on Intellectual Property, Innovation and Public Health, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland. zuckerh@who.int*