

DRUG RESEARCH

WHO Panel Weighs Radical Ideas

Lifesaving antiretroviral drugs have been available for a decade in wealthy countries, yet millions of HIV-infected people south of the equator still can't get them. The medicine cupboard is equally bare for people afflicted by tropical illnesses such as visceral leishmaniasis, sleeping sickness, and Chagas disease, for which there are no truly good therapies. Western medical science has not done well by the world's poor, and some critics blame this on its reverence for intellectual property (IP). Is it time to overhaul the IP protection system? A new working group hosted by the World Health Organization (WHO) will consider that question in a series of meetings beginning next week in Geneva, Switzerland.

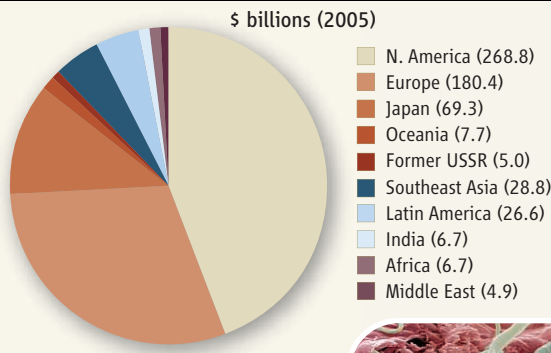
Critics of the current IP protection system hope that WHO's Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property will reform—or even hack down—the still-expanding worldwide patent system. They say it puts lifesaving new drugs beyond the reach of poor patients and hampers development of new medicines for tropical diseases. But others, including the pharmaceutical industry, argue that the IP protection system isn't the real problem and that the talks in Geneva risk distracting people from practical solutions. The IGWG—whose members will include representatives of governments as well as nongovernmental organizations—appears “motivated by anticapitalism rather than logical thinking about how to get drugs to patients,” says Trevor Jones, a former director of research and development at the Wellcome Foundation.

Patents are designed to spur the invention of new products. But they also allow companies to charge high prices, putting people without purchasing power at a disadvantage. Many critics say it is not enough to help the poor get access to drugs; the system's incentives must be changed. To produce new drugs for neglected diseases, they say, the world needs a new R&D system that rewards not market sales but the potential to save lives and improve health.

One such framework, which the IGWG

may consider, is a hotly debated proposal for an international treaty to open up drug discovery, championed since 2002 by James Love, director of the Consumer Project on Technology in Washington, D.C. Under Love's “R&D Treaty,” countries would agree to spend a minimum percentage of gross domestic product on medical

World Pharmaceutical Market by Region



No profit? A minuscule pharmaceutical market in developing countries limits R&D on drugs against trypanosomes, which cause African sleeping sickness and Chagas disease.

research, including a portion for neglected diseases. In addition, the treaty would promote open access to research findings and possibly add R&D incentives. For instance, governments could award big monetary prizes for those who invent important new medicines. Manufacturers would then be free to produce and market them cheaply.

The treaty, recommended in a letter to the World Health Assembly by 162 scientists, health experts, and others last year, “is widely seen as the end of the pharmaceutical industry as we know it,” says Anne-Laure Ropars, a researcher at the George Institute for International Health in London.

No wonder the industry is vehemently opposed. The treaty would create an “extremely complicated international bureaucracy,” says Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers and Associations in Geneva, adding that the award system would never work. Instead, Noehrenberg

offers a different idea: The world should create markets where they currently don't exist. For instance, companies could be enticed with research grants from a “Global Tropical Disease Fund” or the promise of guaranteed sales should they develop an effective new drug.

The industry also contributes through a model called the public-private partnership (PPP). Over the past 10 years, more than two dozen PPPs have sprung up to tackle diseases of the poor. Enlisting industry, academia, governments, and foundations, these partnerships, such as the TB Alliance and the Medicines for Malaria Venture (MMV), have produced many new candidate drugs (*Science*, 13 January, p. 167). And the IP protection regime has not been an obstacle, says MMV president Chris Hentschel: “If people spent less time thinking about IP and more about other things, we would make more progress.”

But others point out that health PPPs have a narrow base: 60% of their funding comes from a single source, the Bill and Melinda Gates Foundation; governments contribute very little. Moreover, industry tends to help PPPs that work on diseases that affect both the poor and people from rich countries, such as malaria and TB, says Els Torreele, project manager at the Drugs for Neglected Diseases Initiative. Given the scope of the problem, something more radical is needed, she says.

Whether the IGWG can deliver a solution remains to be seen. The group's predecessor at WHO, the Commission on Public Health, Innovation, and Intellectual Property Rights, issued a raft of recommendations in April—such as increasing contributions to PPPs and building clinical trial capacity—but could not agree on some key patent issues. Some predict that when the IGWG issues its final report to the World Health Assembly in May 2008, it may propose ways to implement the less controversial parts from the April review rather than a radical reform.

But Love thinks the world may be ready for a change. He notes that, although the U.S. government has generally aligned itself with the pharmaceutical industry, it strongly supported increased access to HIV drugs in Africa. It also unexpectedly voted for the resolution introduced by Kenya and Brazil that called the IGWG into existence. (The drug companies and the European Commission opposed the plan.) Love is hoping for another surprise.

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