



WHO plans for neglected diseases are wrong

Research and development into diseases affecting the world's poorest people will not benefit from the agency's policy, warns Mary Moran.

After more than a decade of trying to find a way to fund research on diseases that affect the developing world, the World Health Organization (WHO) made a decisive move last month when it announced its first pilot projects. As *Nature* reported (see *Nature* 505, 142; 2014), the WHO hopes that these projects will break the stalemate over research on neglected conditions such as kala-azar, a deadly parasitic disease that afflicts hundreds of thousands of the world's poorest people.

The WHO is taking giant strides, but they are in the wrong direction. The projects are based on flawed logic and will waste time and money. Worse, this initiative could actively damage existing projects to develop such medicines. The WHO pilot should be stopped.

I do not make these claims lightly. I was involved in the WHO analysis, drafting and recommendations, and know how difficult it has been.

The pilot projects are the culmination of a ten-year negotiation that aimed to achieve two goals: to make commercial medicines more affordable for the developing world, and to stimulate public (non-profit) development of medicines for neglected diseases.

The first goal demands complex and contentious efforts to change or replace the commercial pharmaceutical system, which funds its drug research and development (R&D) programmes by charging high prices to patients. This means that new commercial medicines for cancer, blood pressure or AIDS are often priced out of reach of the poor. Proposed alternatives to increase access would replace drug companies' exclusive patents, substitute company profits with public research prizes and develop a parallel, publicly funded pharmaceutical system. There has been no progress on this.

The second goal is to increase government efforts to develop medicines for non-profit neglected diseases such as malaria, sleeping sickness and parasitic infections. But this not-for-profit work was well under way long before the WHO announced its pilot projects. Governments and philanthropists were investing US\$3 billion a year into research for neglected diseases, with more than 360 pharmaceutical projects in the pipeline, thousands of back-up research projects and some 40 neglected-disease drugs already being used by patients in the developing world. The pipeline was good, but the work needed more funding and better coordination between the many funders.

The WHO's motives were (and remain) good, but it made the crucial mistake of conflating these two issues. Almost from the start, the agency assumed that profits and patents were the problem not only for access to commercial medicines (they are), but also for not-for-profit public research (they aren't). And,

wanting to take on the commercial model, but unwilling to front up to industry, the WHO chose instead to play out its fight in the neglected diseases. The agency insisted that the pilot projects — all publicly funded, non-profit efforts — must target both goals: to make new medicines and to trial R&D models designed to break commercial patents and profits.

This makes no sense. Innovative R&D models that replace sales revenues, remove monopoly commercial patents or replace commercial profits with public funding can be piloted only in areas that have sales revenues, patents and profits — that is, in commercial areas. Neglected diseases by definition have no profits (that is their problem in the first place), and their R&D has never been funded from sales revenues (which do not exist in impoverished regions). Neglected-disease R&D is a non-profit area that has always been funded by government and

philanthropic grants, with almost all the resulting products sold in poor countries at low- or non-profit prices. The WHO has set up a false battle.

The agency's approach has knock-on effects. First, it creates deep confusion among governments and public-health experts, and turns two potentially solvable problems into one insoluble Gordian policy knot. Funding of neglected diseases cannot be achieved by attacking commercial patents; and commercial access should not be gained by setting up a parallel public R&D system. The two problems need to be separated. The most recent World Health Assembly was painful proof of this, with the neglected-disease proposals sinking to the bottom along with the commercial-access millstone.

Second, WHO actions are in danger of helping to defund and shut down the successful not-for-profit pipeline of drugs for the developing world. Government funding of not-for-profit product development is down \$120 million on 2009, and product-development partnerships are down \$156 million. Instead of encouraging donors, the WHO is sending a message that a new R&D approach is needed, and setting up its own R&D pilot in competition.

The agency's pilot process runs a poor second to the existing neglected-disease R&D pipeline. It has no clear priorities, and the final eight projects add little value: half are re-announcements of existing work; others are low-innovation tweaks rather than priority medicines. The pilot proposals should be dropped — they are bad policy all round. The agency should instead focus on real solutions to improve access to commercial medicines — the most pressing need for the world's poor. And it should get behind the existing neglected-disease pipeline and urge funders to do the same. ■

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