Medicines without barriers

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TWO events, two statements, separated by just six weeks. On 14 April, a declaration from the heads of government of six nations saluted the open collaboration of scientists who had completed the human genome sequence. On 2 June, leaders at the G8 summit in Evian released an action plan on health that continued to emphasise the existing closed commercial system of drug development and intellectual property protection. These contradictory statements reflect the current dogma: academic science is good for generating new ideas, but to turn ideas into practical products such as drugs, commercial discipline is required.

Yet the AIDS crisis has brought to public notice what has always been generally true - that this system leads to high drug prices and unequal access. It doesn't have to be this way. We are proposing an alternative model, a World R&D Treaty, that would allow countries to satisfy trade obligations using open research for drug development. The success of the Human Genome Project has shown that cooperation can be a very productive basis for research.

Today's high drug prices are a consequence of intellectual property enforcement mechanisms that are designed to pay for the R&D done by drugs companies and stop the "free rider" effect, whereby companies manufacture and sell copies of drugs that other companies spent large amounts of money developing. These mechanisms have the unpleasant side effect of making it the primary responsibility of pharmaceutical companies to maximise return on investment, which inflates drugs prices beyond what many people can pay.

What is less well recognised is that this system is an enormously inefficient way of purchasing R&D. There is a considerable lack of transparency in pharmaceutical R&D investment, but the available data indicates that only about 10 per cent of drug sales goes towards R&D. Much of what is reported as R&D is related to marketing, or to products that do not offer significant therapeutic advantages over existing medicines.

If prices did not have to cover the cost of R&D, drugs would not need intellectual property protection. If knowledge about the manufacture of drug compounds were in the public domain, drugs could become a freely traded commodity. As a result they would be cheaper, as happens now when a patent expires. Such a model would need to overcome two problems: how to pay for R&D if sales of the product no longer contribute to it, and how to ensure R&D expenditure leads to new drugs.

The US National Institutes of Health has already developed a number of important drugs for severe illnesses, such as taxol (cancer) and ddI (AIDS), showing that publicly funded research can lead to commercially viable products. The Human Genome Project demonstrated in another setting that major R&D-based "products" can be delivered without commercial incentives. It also showed how openness not only benefits the science, but can also improve the efficiency of R&D projects. This openness allowed continuous evaluation of progress by funding agencies and gave incentives to the different genome sequencing centres both to perform and to share new ideas, since they received "credit" for helping overall progress. Openness, external assessment and notions of credit are not new: basic science is driven by this through peer review.

So where would the money come from to pay for the R&D? Analysis of worldwide drug expenditure shows

that spending varies little from 1 per cent of GDP in most developed and developing countries. Assuming that about a tenth of revenue from the sale of drugs is ploughed back into R&D, that amounts to about 0.1 per cent of GDP. To avoid "free riders", countries could be obligated to fund R&D up to a certain percentage of GDP. This could replace the current trade rules, which focus only on a detailed specification of intellectual property rules. Countries could then decide if they wanted to follow a strictly closed system, with high drug prices for 20 years, or experiment with new open development models.

We have developed practical proposals to turn these ideas into a treaty proposal at a variety of workshops on intellectual property, including a meeting held in Geneva in April organised by Médecins sans Frontières, Oxfam, Health Action International and the Consumer Project on Technology, and a recent meeting of healthcare economists in Marseille. Next January, the World Health Organization's executive board will meet in Geneva to agree on terms of reference for a new evaluation of intellectual property, innovation and public health, and in November 2004 there will be a world summit on healthcare R&D in Mexico. We should use these opportunities to develop a new trade framework that works for the public good rather than for the benefit of the lucky few.

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