

which reports acute poverty in 104 developing countries, shows that India ranks below Bangladesh, and that India has 845 million MPI poor people, more than 26 sub-Saharan African nations put together. This is not surprising, given that one in five households does not have a single person with primary school education, one in four households has had a child die, two in five households have malnourished children or adults, one in eight has no access to clean drinking water and one in two has no access to its own sanitation facility (6). In this context, what trickle-down effect can we claim for our globalising and growing economy?

As described in the Commission's extensive review, without remedying social determinants there can be no chance of sustainably improving healthcare. Action is needed now and from multiple players -- the WHO, other multilateral agencies, national and local governments, civil society, the private sector, and research institutions studying economics, health and development. The National Rural and Urban Health Missions are evidence of commitment, but words need to be supported by deeds. Transparency and action are needed across various fields, not just in health.

Reducing health inequities is, for the Commission on Social Determinants of Health, an ethical imperative. There are two possibilities - the first being that we do not change and things

stay the way they are. The second is that we try to change things and make opportunities for health and development in a universal social support framework giving everyone equal access and care and that way we could go far. As stated in the report, "it is the right thing to do, and now is the right time to do it"

References

1. Commission on Social Determinants of Health. *Closing the gap in a generation: Health equity through action on the social determinants of health*. Geneva: World Health Organization; 2008.
2. Department of Public Information, United Nations. Economic Social Council Resolution 6447 [Internet]. New York: UN. 2010 Jul 21 [cited 2010 Sep 11]. Available from: <http://www.un.org/News/Press/docs//2010/ecosoc6447.doc.html>
3. United Nations General Assembly. Resolution. United Nations Millennium Declaration [Internet]. New York: United Nations. 2000 Sep 8 [cited 2010 Sep 11]. Available from: <http://www.un.org/millennium/declaration/ares552e.pdf>
4. Hanlon P, Lawder R S, Buchanan D, Redpath A, Walsh D, Wood R, Bain M, Brewster D H, Chalmers J. Why is mortality higher in Scotland than in England and Wales? Decreasing influence of socioeconomic deprivation between 1981 and 2001 supports the existence of a 'Scottish effect'. *J Pub Health (Oxf)*. 2005 Jun;27(2):199-204.
5. The Self Employed Women's Association of India (SEWA) [Internet]. [cited 2010 Sep 11]. Available from: <http://www.sewainsurance.org/childcare.html>
6. Alkire S, Santos ME. *Multidimensional Poverty Index* [Internet]. Oxford: Oxford Poverty and Human Development Initiative 2010 Jul [cited 2010 Sep 11]. Available from: <http://www.ophi.org.uk/policy/multidimensional-poverty-index/>

The Health Impact Fund: a potential solution to inequity in global drug access

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Abstract

Global health inequities persist despite significant increases in funding and a growing number of global health initiatives. Especially vulnerable to disease, the poor majority of the world's population currently cannot afford advanced medicines, and the diseases confined to the poor receive little attention from pharmaceutical research. As a complement to the existing intellectual property regime, we have proposed the Health Impact Fund (HIF) as a mechanism that would create incentives for the development and optimal promotion of new high-impact medicines sold at the cost of manufacture. In this article, we outline the HIF and its ethical significance.

Background

Although global development assistance for health has increased greatly in recent years (1), large rich-poor health gaps remain within and among countries, even though the number of global health initiatives and the number of interested international and local stakeholders continue to rise (2). Consequently, there have been calls for improved matching of funding and resources from global health initiatives to local needs (3). In addition, better health impact assessment is required within health systems so that changes can be properly measured. Impact assessment is needed alongside effective interventions and treatments and capacity building, in order to realise sustainable improvements in health (4). Discrete,

“vertical” programmes for individual diseases are unlikely to alleviate health disparities and a more integrated system change is necessary (4).

It is well known that lack of access to drugs and lack of research on diseases that cause a majority of the global disease burden are major obstacles to bridging these health inequalities (5-8). The current patent monopoly rights under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement (9) have widened the health gap within developing countries as well as that between developing and high-income countries, even though patent protection and drug affordability are not the only factors contributing to access problems (10-12).

In response to these problems, we have proposed the Health Impact Fund (HIF) as a complement to the existing intellectual property regime. It would create incentives for improving access to medicines as well as for research and development of drugs for neglected diseases (13-14). The HIF would be a global agency, underwritten by governments, which would offer pharmaceutical innovators the option to register any new product. Registration entitles the innovator to receive, for a defined period (e.g. 10 years), a share of fixed annual reward pools. The fund would disburse at least US\$6 billion yearly, distributing this money over registered medicines in proportion to their respective contributions to global health as estimated with a global health impact assessment exercise. In exchange, the registrant would agree to sell the medicine wherever it is needed at no more than the lowest feasible cost of production and distribution and also to offer, after the end of the reward period (if any patents remain unexpired), free licences to enable generic manufacture and sales.

Since 2005 (15), the idea of the Health Impact Fund has gathered momentum in terms of academic publications, discourse, and publicity in scientific and broader media (16-19). The World Health Organisation’s Expert Working Group has issued a welcome endorsement of the HIF as “promising” and deserving of further examination, alongside open source drug development, patent pools, a priority review voucher scheme, and orphan drug legislation (20). These mechanisms have great potential for improving access to new drugs in developing countries. A multi-disciplinary group of international experts is currently working on refining the health impact assessment tools that the HIF would use and on designing pilot projects in low- and middle-income country settings.

Moral arguments for reforming the existing rules governing pharmaceutical innovation

Any morality condemns avoidable human suffering and premature death. By rewarding pharmaceutical innovators with temporary monopolies on any new medicines they invent, the existing patent regime (TRIPS) does much better by this standard than a free market would do. (In a free market, it would be irrational to undertake the labours of developing a new medicine because innovators could not recoup their research and development expenses, because of competing suppliers who cheaply reverse-engineer their innovation.)

But we can do much better still, by the same standard, if we add the HIF as a complementary reward mechanism: moving from TRIPS-pure to TRIPS+HIF. There are three reasons for this.

1. The HIF would attract more pharmaceutical research toward diseases concentrated among the world’s poor. When innovators can be rewarded only with patent-protected mark-ups, then such diseases – no matter how widespread and severe – are not attractive targets for pharmaceutical research. This is so because the demand for such a medicine drops off very steeply as the patent holder enlarges the mark-up. There is no prospect, then, of achieving high sales volume and a large mark-up. Moreover, there is the further risk that a successful research effort will be greeted with loud demands to make the medicine available at marginal cost or even for free, which would force the innovator to write off its initial investment as a loss. In view of such prospects, biotechnology and pharmaceutical companies predictably prefer even the trivial ailments of the affluent, such as hair loss and acne, over tuberculosis and sleeping sickness. This problem of neglected diseases is also known as the 10/90 gap, alluding to only 10% of all pharmaceutical research being focused on diseases that account for 90% of the global burden of disease (21). Malaria, pneumonia, diarrhoea, and tuberculosis, which together account for 21% of the global burden of disease, receive 0.31% of all public and private funds devoted to health research. And diseases confined to the tropics tend to be the most neglected: of the 1,556 new medicines approved between 1975 and 2004, only 18 (some of them by-products of veterinary research or commissioned by the military) were specifically indicated for tropical diseases and three for tuberculosis (22). The HIF would produce a continuous stream of effective remedies against diseases that have been allowed to inflict enormous harm on human health.
2. HIF-registered products would be sold at the lowest feasible cost of manufacture and distribution and would therefore be affordable from day one even to poor patients. Under the TRIPS-pure system, by contrast, medicines still under patent are sold near the profit-maximising monopoly price which is largely determined by the demand curve of the affluent. When wealthy people really want a drug, then its price can be raised very high above the cost of production before increased gains from enlarging the mark-up are outweighed by losses from reduced sales volume. With patented medicines, mark-ups above 1,000% are not exceptional. When such exorbitant mark-ups are charged, only a few of the poor can have access through the charity of others – much larger numbers suffer and die.
3. The HIF would greatly enhance the incentives of innovators to create and support the conditions – proper drug storage, diagnosis, prescribing, adherence – that allow their registered product to have its optimal effects. The existing TRIPS-pure system rewards the mere *selling* of high-priced patented medicines. Even in affluent countries, pharmaceutical companies have incentives only to sell

products, not to ensure that these are actually used, to optimal effect, by patients who really need them. This problem is compounded in poor countries, which often lack the infrastructure to distribute medicines as well as the medical personnel to prescribe them and to ensure their proper use. In fact, the present regime even gives pharmaceutical companies incentives to *disregard* the medical needs of the poor. To profit under this regime, a company needs not merely a patent on a medicine that is effective in protecting paying patients from a disease or its detrimental symptoms. It also needs this target disease to thrive and spread because, as a disease waxes or wanes, so does market demand for the remedy. Affluent people living or travelling in Assam would not be buying expensive anti-malarials, for example, if malaria were not proliferating among Assam's poor. A pharmaceutical company helping poor patients to benefit from its patented medicine would be undermining its own profitability in three ways: by paying for the effort to make its drug competently available to them, by curtailing a disease on which its profits depend, and by losing affluent customers who find ways of buying, on the cheap, medicines meant for the poor. These highly regrettable disincentives would be radically reversed for HIF-registered products as these are rewarded only if, and insofar as, they cause measurable health improvements. Having registered a product with the HIF, an innovator will have a powerful profit motive to help overcome any obstacle between this medicine and its optimal health impact. Such an innovator would profit maximally if its product were to wipe out the disease completely.

In these three ways, the HIF would greatly enhance the global health impact of medicines, even while, at US\$6 billion per annum, it would add less than one percent to what the world already spends on pharmaceuticals. Moreover, much of this US\$6 billion would not even be additional money. In many cases, an HIF-registered medicine would have been developed even in the absence of the HIF, with the innovator gaining rewards from high patent-protected mark-ups rather than through tax-funded health impact rewards. In these cases, much of the cost to taxpayers comes back to them through lower drug prices, lower insurance premiums, lower national health system expenses, and lower contributions to international agencies, such as UNICEF or the Global Fund. The crucial difference is that, by paying for pharmaceutical innovation through health impact rewards, rather than through patent-protected mark-ups, we need not exclude from advanced medicines the world's poor: those who can afford the competitive market price of the drug, but not the vastly higher monopoly price.

Some believe that it is morally acceptable to continue TRIPS-pure because this system merely fails to benefit poor people, something no one is really morally required to do. This belief is gravely mistaken and doubly so. It is not morally acceptable to fail to benefit people at low cost, when their health or even lives are at stake. Even more importantly, the enforcement of patents is not a mere failure to benefit; it is a case of active harming. Before TRIPS came into force, generic manufacturers (most

commonly from India), constrained only by process patents they usually managed to innovate around, profitably offered cheap generic versions of new medicines to India's poor and to the poor of the world. By suppressing these mutually beneficial transactions, the designers and enforcers of the new TRIPS-required product patents are actively cutting poor people off from the medicines they desperately need.

But do not new medicines morally belong to their inventors, and are not such inventors entitled actively to defend their property? Here the cleverly chosen expression "intellectual property" suggests exactly the wrong answer. By preventing a willing Indian generic manufacturer from supplying its products to willing patients at mutually agreeable prices, innovators aren't defending what they legitimately own. It is not they, but the generic manufacturer, who owns the raw materials. And how can it be legitimate to unilaterally divest this manufacturer of its right to transform these materials into products of a certain kind, simply by making a product of this kind first? The idea that any human agent has a natural right to unilaterally divest all others of their freedom to use their own raw materials is bizarre. Intellectual property rights must then be justified - as they nearly always have been justified - by appeal to their social value or usefulness. And by this standard, as we have seen, the TRIPS+HIF system is vastly superior to TRIPS-pure.

Advantages of the HIF for different stakeholders

Unlike advance market commitments (AMCs) (23), the HIF is not disease-specific and is thus much less vulnerable to lobbying by firms and patient groups. It simply offers to reward *any* new medicine that works, in proportion to how well it works, provided that the innovator agrees to sell it at cost. This can also include the development of new uses for existing products, efforts that are not rewarded under TRIPS-pure. The HIF thus pulls research toward the medicines that can do the most good. Analogously, the HIF also re-orientates the innovation and marketing priorities of the pharmaceutical industry toward health impact. By greatly increasing the health impact of pharmaceutical spending in these ways, the HIF would benefit (relative to the status quo) patients and insurers.

The HIF would also benefit pharmaceutical firms. It would broaden the range of research projects they can profitably undertake and would, in particular, transform the more damaging diseases of the poor into lucrative profit opportunities. Because HIF-registered new medicines for such diseases would be sold at cost, firms would not have to exclude large numbers of poor patients and would not face popular protests and resentment. To the contrary, they would benefit from their pioneering work, through name recognition and respect in developing countries, where they can then find a better reception also for their other products. In some cases, a product that would have been profitable if sold with a patent-protected mark-up, may be even more profitable with HIF-registration. Here, too, innovators can benefit: by making more money and through a much better public image. And it is always their own decision whether to register some specific product or not.

The HIF will be financed through tax contributions from all around the world. But taxpayers will reap compensating benefits. They will benefit from much-reduced prices of some important medicines as well as from the existence of high-impact medicines that, without the HIF, would not have been available at any price. The HIF mechanism would ensure that taxpayers always obtain good value for money since any HIF-registered product will cost less per unit of health impact than products outside the HIF (13). Taxpayers would also benefit from a reduction in risks of pandemics and other health problems that easily cross national borders.

Conclusion

Current health disparities due to lack of access to medicines are morally unjustifiable. The existing TRIPS-pure regime provides inadequate incentives for the pharmaceutical industry to develop treatments for diseases that account for most of the world's disease burden. The HIF would offer a complementary mechanism through which products tackling these diseases would be rewarded in proportion to their global health impact. The existing TRIPS-pure regime also ensures that the more advanced existing treatments are priced out of the reach of the majority of the human population. All HIF-registered products would be sold everywhere at the lowest feasible cost of manufacture and distribution. Quite apart from the global health gains it would produce, the creation of the HIF can also be justified to all relevant stakeholders separately. So what are we waiting for?

References

1. Ravishankar N, Gubbins P, Cooley RJ, Leach-Kemon K, Michaud CM, Jamison DT, Murray CJ. Financing of global health: tracking development assistance for health from 1990 to 2007. *Lancet*. 2009;373:2113-24.
2. Hanefeld J. How have global health initiatives impacted on health equity? *Promot Educ*. 2008;15(1):19-23.
3. Chalkidou K, Levine R, Dillon A. Helping poorer countries make locally informed health decisions. *BMJ*. 2010;341:c3651.
4. Swanson RC, Mosley H, Sanders D, Egilman D, De Maeseneer J, Chowdhury M, Lanata CF, Dearden K, Bryant M. Call for global health-systems impact assessments. *Lancet*. 2009;374:433-5.
5. *Global Poverty Report* [Internet]. Okinawa: African Development Bank, Asian Development Bank, European Bank for Reconstruction and Development, Inter-American Development Bank. International Monetary Fund, World Bank; 2000 Jul [cited 2010 Sep 26]. Available from: http://www.adb.org/Documents/Reports/Global_Poverty/2000/G8_2000.pdf
6. World Health Organization. *The world drug situation*. Geneva: WHO;1988.
7. World Health Organization. *Chronic Diseases Report 2005, Chapter 2: chronic diseases and poverty* [Internet]. Geneva: WHO;2005[cited 2010 Oct 1]. Available from: http://whqlibdoc.who.int/publications/2005/9241563001_eng.pdf
8. Lown B, Banerjee A. The developing world in *The New England Journal of Medicine*. *Global Health*. 2006 Mar 16;2:3.
9. World Trade Organisation. *Agreement on trade-related aspects of intellectual property rights* [Internet]. Geneva: World Trade Organization; 1994 [cited 2010 Oct 1]. Available from: http://www.wto.org/English/tratop_e/TRIPS_e/trips_e.htm
10. Attaran A, Gillespie-White L. Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa. *JAMA*. 2001;286:1886-92.
11. Oliveira MA, Bermudez JA, Chaves GC, Velásquez G. Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health? *Bull World Health Organ*. 2004;82:8150-221.
12. Attaran A. How do patents and economic policies affect access to essential medicines in developing countries? *Health Affairs (Millwood)* 2004;23:155-66.
13. Hollis A, Pogge T. The Health Impact Fund. *Making new medicines accessible for all* [Internet]. Incentives for Global Health; 2008[cited 2010 Sep 26]. Available from: <http://www.healthimpactfund.org>
14. Banerjee A, Hollis A, Pogge T. The Health Impact Fund: incentives for improving access to medicines. *Lancet*. 2010;375:166-9.
15. Pogge T. "Human Rights and Global Health: A Research Program." In: Barry C, Pogge T, editors. *Global institutions and responsibilities*. Oxford: Blackwell Publishers; 2005. p. 190-217.
16. Vogel L. Fund proposed to pay for drugs with greater global impact. *CMAJ*. 2010;Mar 23:E231-2.
17. Morris K. Health impact fund promotes drug access and innovation. *Lancet Infectious Diseases*. 2009;9:83.
18. Spiegel JM, Dharamsi S, Wasan KM, Yassi A, Singer B, Hotez PJ, Hanson C, Bundy DA. Which new approaches to tackling neglected tropical diseases show promise? *PLoS Med*. 2010 May 18;7(5):e10002555.
19. Singer P. Tuberculosis or hair loss? Most medical research targets conditions that kill relatively few people. A global research fund could change that. *The Guardian* [Internet]. 2008 Sep 16 [cited 2010 Sep 26]. Available from: <http://www.guardian.co.uk/commentisfree/2008/sep/16/health.pharmaceuticals>
20. World Health Organization. *Public health, innovation and intellectual property: Report of the Expert Working Group on Research and Development Financing* [Internet]. Geneva: WHO; 2009 Dec 23 [cited 2010 Sep 26]. Available from: http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_6Add1-en.pdf
21. Bosman M, Mwinga A. Tropical diseases and the 10/90 gap. *Lancet*. 2000 Dec;356 Suppl:s63.
22. Chirac P, Torreele E. Global framework on essential health R&D. *Lancet*. 2006 May 13;367:1560-1.
23. Hollis A. *A Comprehensive Advanced Market Commitment* [Internet]. Submission to World Health Organization Public Hearing on Public Health, Innovation and Intellectual Property. 2007 Sep [cited 2010 Sep 26]. Available from: www.who.int/phi/public_hearings/second/contributions_section2/Section2_Aidan_Hollis_Full_Contribution.pdf