The Health Impact Fund: Pay-for-Performance

INTRODUCTION

In an ideal world, pharmaceuticals would serve the purpose of improving health. By offering to reward firms on the basis of their contribution to this purpose, the Health Impact Fund would stimulate innovation without impeding access through high prices. It would focus the attention of pharmaceutical innovators on the most cost-effective ways of improving global health through new medicines.

The HIF is an integrated solution that requires low prices worldwide, while offering innovative companies direct payments based on the health impact of their innovations, no matter where the health impact occurs. The HIF will thus make it profitable to develop medicines for heretofore neglected diseases as well as medicines with global impact. These medicines will be sold at low prices everywhere, while still generating solid returns for innovative pharmaceutical companies and their shareholders. By reorganizing the way we pay for some drugs, the HIF realigns incentives while extending access. It ensures that global pharmaceutical expenditures and innovator profits are matched by much greater health improvements.

The essence of the proposal is to offer firms a share of a fixed fund for each of ten years, in proportion to the share of health impact of their registered product out of all registered products. For example, if all registered products were estimated to have saved twenty million "Quality-Adjusted Life Years" (QALYs), a registered product that had saved two million of these QALYs would receive ten percent of the fund. This calculation would be performed annually based on current data, and each registered product would receive annual payments for ten years following market approval. In exchange, the firm would give up the opportunity to earn profits on sales of its registered drug and would offer a royalty-free open license for generic versions of the product following the reward period. Firms could choose whether to register any particular product for health impact rewards or to exploit their monopoly pricing privilege in the usual way.

Core funding for the HIF would be provided by partner countries that agree to support it. A reasonable starting level would be $6 billion per year. At this rate, the HIF could support the development of about two new drugs annually, sustaining a stock of about twenty medicines. If the HIF works well, it can be scaled up so as to increase the number of widely accessible innovations it induces and sustains.

The HIF allows market forces to set the dollar-per-QALY rate, relying on new medicines that would be commercially viable with or without registration. If the reward rate were excessive, new products would be registered, resulting in an automatic reduction of the rate; and if the reward rate were too low, new products would not be registered, or registered products would be withdrawn, leading to higher rewards for the remaining registrants.[1] Market forces will also determine sales volumes of registered medicines without the monopoly price distortions otherwise typical of pharmaceutical markets. In many countries, pharmaceutical pricing is largely controlled by governments.

[1] Note that while some products might be much better rewarded inside the HIF, others would be approximately indifferent between monopoly pricing and the HIF. It is the latter group which would effectively establish the reward rate.

The HIF would employ a method for determining payments to innovators that is more transparent and less subject to influence than the mechanisms used by state and private insurers today. And unlike systems in which research is funded directly, the HIF would not set research priorities: it would merely reward successfully developed products based on their assessed impact. Decisions about which molecules should be explored and tested and about how to allocate research funds among diseases would be left to pharmaceutical innovators with a financial stake in the decision. Of course, direct funding by governments would continue to be an important source of investment into pharmaceutical research; the HIF could complement such funding by enabling distribution of the resulting drugs at the cost of production. The HIF is thus more market-oriented than existing systems of financing pharmaceutical innovation and less prone to creating distortions. It will pay strictly on the basis of performance.

WHY THE HEALTH IMPACT FUND IS NECESSARY

The global pharmaceutical industry should create new medicines that are important to global health and to enable people all over the world to benefit from these products once they are known to be safe and effective. The HIF is specifically designed to make this happen: it ensures low prices to facilitate access and it guides innovators to seek the greatest health impact when they decide what products to develop and how to market them. A focus on health impact benefits all—and especially the poor, because they suffer greater disease burdens and because the HIF rewards improvements in their health at the same rate as health gains among the more affluent. The HIF makes it profitable for innovators to develop medicines for diseases concentrated among the poor and to ensure that poor people can optimally benefit from all HIF-registered products. Thus, HIF registrants would have incentives to help reduce non-price barriers facing the poor, such as gaps and inefficiencies in pharmaceutical distribution networks, flight of skilled doctors and nurses, lack of diagnostic tools and other inadequacies in primary care systems.

Currently, diseases concentrated among the poor are "neglected diseases." There has certainly been welcome progress in addressing such diseases, much of it due to an increase in charitable contributions. Public-Private Partnerships (PPPs) and Product-Development Partnerships (PDPs) have successfully enhanced the rate of development of new drugs, and it is to be hoped that the HIF could complement PPPs and PDPs by creating a mechanism by which such partnerships could benefit from a financial reward while helping to fulfill the legitimate goals of widespread access at the lowest possible prices.[2]

Patented medicines for global diseases, which affect people everywhere, tend to be sold at high prices that exclude many buyers even in affluent countries. Differential pricing between rich and poor consumers, within or across countries, is difficult: arbitrageurs will try to buy the good cheaply and resell it at the higher price. Even without parallel trade, there is a network of international price comparisons which makes it hard for firms to charge different prices in different countries.

The HIF avoids these problems by requiring registered products to be sold to rich and poor alike at a competitive price. Innovators are rewarded not for selling their

[2] See Pharmaceutical R&D Policy Project. 2005. *The Landscape of Neglected Disease Drug Development*. London: Wellcome Trust and London School of Economics.

product but for its effect on public health worldwide. In this way, the incentives of the pharmaceutical industry are precisely aligned with social goals. Rather than look to the pharmaceutical companies for philanthropy, the HIF offers them the opportunity of market-based rewards for the contribution their products make to improving global health. The HIF will thus benefit investors, researchers, and wealthy and poor patients alike. Of course, these benefits come at a cost: governments and private foundations will have to finance the Fund for it to be able to reward innovators. The costs are however reduced to the extent that low prices on registered medicines yield savings to buyers who would otherwise have paid high prices. And the remaining net cost is balanced by large health gains due to additional innovation and increased access.

The HIF would not merely stimulate the development of medicines that are unprofitable in its absence. Products such as Plavix (which helps prevent heart attacks and strokes) could offer therapeutic value throughout the world, and yet their sales tend to be concentrated in the wealthiest countries due to relatively high prices. If rewarded under the HIF, such products could see enormously expanded sales volumes because of lower prices. Depending on the scale of funding of the HIF, this could be a more profitable way of selling such drugs—and it would be of tremendous value to patients all over the world.

PROPERTIES OF THE HEALTH IMPACT FUND

The HIF's approach to solving problems of innovation and access is straightforward: pay directly for what is valuable, and don't ration access on the basis of artificially high prices. This simple and intuitively compelling approach has many attractive characteristics.

- The mechanism of the HIF is designed to provide innovation incentives whose strength is proportional to the social value of the innovation as measured by health impact. No other approach to paying for innovation has this desirable property. The patent system places a value on an innovation based on people's willingness to pay which, for essential medicines, is closely related to their ability to pay. It therefore provides much greater rewards for addressing the health needs of the wealthy than those of the poor. The HIF redresses this imbalance and motivates firms to invest in research with the greatest impact on health.
- By ensuring low prices, the HIF removes a substantial obstacle that makes new drugs inaccessible to the poor and provides substantial cost savings to everyone else.
- The low price of HIF medicines reduces the incentives for counterfeiting, which blights pharmaceutical markets, especially in developing countries. Counterfeit drugs harm not only manufacturers but, when they fail to contain the correct amounts of the relevant active ingredients, may also harm patients and, in the case of communicable diseases, people everywhere (by causing development of disease-resistant strains).
- The HIF is ethically attractive because it solves the problem of obtaining innovation without blocking access through artificially high prices.
- The HIF is scalable: if it works well, it can be expanded by increasing the amount of funding available.

- The HIF has a clear objective and straightforward rules. It requires relatively little administrative discretion.
- Because the HIF is an optional system, there is an automatic adjustment mechanism to ensure that the payments it makes are reasonable relative to the profits earned on other drugs not registered with the HIF: if payments get to be too high, more products will be registered and rewards will fall as funds are spread over more products. The reverse effect operates if payments fall too low. Such automatic adjustment limits the funding partners' risk of excessive payments as well as potential registrants' risk of inadequate rewards.
- The HIF helps addresses the "last mile" problem of getting drugs to poor people who need them. While the present regime provides large rewards for exposing affluent people to patented medicines even when these provide no health benefits, it provides no rewards for bringing such a medicine to poor people even if their lives depend on it. In the HIF system, registrants will be financially motivated to encourage appropriate use of their products among the rich and the poor alike, because rewards depend on the number of people served and on the magnitude of the health benefits these people derive.
- The citizens of wealthier countries benefit not only directly from lower drug prices and a greater industry focus on achieving actual health impact, but also indirectly from improved health in developing countries which has global benefits in terms of economic growth and reduction in the development and spread of harmful pathogens.
- The HIF can reduce expenditures by pharmaceutical companies on promotional activities and litigation. To the extent that pharmaceutical companies can reduce such wasteful competitive expenses, they will obtain higher profits and will be more strongly motivated to innovate and to register their products with the HIF.

It is instructive here to compare the HIF to the Advance Market Commitments (AMCs) espoused by the G8 finance ministers. What makes the HIF different is that (1) it applies to all kinds of pharmaceutical products that improve human health, and not just to one particular pre-specified vaccine; (2) it does not require a body of experts to set a price, since the reward paid under the HIF arises endogenously from choices by firms about which products to register in the HIF; (3) it creates incentives for early-stage R&D because it is not exclusive about the products that can be registered; and (4) it rewards the innovator on the basis of the health benefits this medicine actually brings to patients rather than through subsidies. For supporting R&D on specific vaccines, AMCs are an effective mechanism. But for pharmaceuticals generally, the HIF is arguably the best mechanism for inducing innovations that will be widely accessible.

In summary, as a mechanism for incentivizing innovation in and access to essential medicines, the HIF has a unique combination of advantages.

THE HIF IS NOT CHARITY FOR THE DEVELOPING WORLD

In the wake of the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which has introduced stronger pharmaceutical patent protections into the less developed countries, much greater attention has come to be focused on the deplorable health care situation of the world's poor. Many—including some of those who have pushed hardest for or benefited the most from the much-

strengthened intellectual property regimes—have adopted the cause of improving the health of the world's poor and are directing billions of dollars to it. Many others have developed interesting and promising ideas about how this can best be done. Is the Health Impact Fund another such idea?

Yes, and no. Yes, because, properly funded, the HIF would make a huge difference to what health care the world's poor can access. It would have this effect in three main ways. The poor will have immediate access to some new high-impact medicines that would otherwise sell at high, patent-protected prices. The poor will have immediate access to some other new high-impact medicines that would otherwise not have been developed. And the poor will greatly benefit from a newly created motive of pharmaceutical firms: to ensure wide and appropriate use of their products.

No, because the HIF has corresponding benefits also for the affluent. They too will be able to purchase at low prices some new high-impact medicines that would otherwise sell at high prices. This difference will be most obvious to individuals who lack complete drug insurance. But even for people with fully comprehensive drug insurance, the lower prices of HIF-registered drugs will result in lower insurance premiums and national health system expenditures.

The affluent will benefit alongside the poor also from the existence of new medicines that would not otherwise have existed. It is likely that, in the short term, registered medicines will mostly treat communicable diseases of the developing world. But, so long as these diseases are very poorly controlled there, they pose a substantial danger to all of humankind. It is in everyone's interest that the diseases of the poor not be treated with half-measures that lead to drug resistance and new virulent strains, but that they be fully understood and, if possible, eradicated. In the medium to long term, once the "lowest-hanging fruit" in treatments for tropical diseases has been picked, the HIF is likely to become more focused on supporting innovation for global diseases.

The affluent will also benefit greatly from a realignment of pharmaceutical companies' interests with actual health impact. After all, the interest of affluent people is not in maximizing their medicine consumption as measured in dollars, but to make rational use of medicines toward achieving better health. Pharmaceutical companies greatly affect the practice of health care in affluent countries: through their decisions about research priorities, the remedies they develop, their influence on the prescription patterns of doctors, and their interactions with national health systems, insurance companies, and legislators. In exerting this influence, these firms are obviously concerned to maximize their profits. And wouldn't it be good for all—rich and poor alike—if these firms' profits on some of their more important medicines were precisely aligned with the health impact these products actually achieve?

The HIF thus is not a way for affluent people or countries to help poor people or countries, but a crucial addition to the established system governing the development and distribution of medicines. Being optional for innovators, the HIF will initially produce some very important medicines for diseases concentrated among the poor—medicines whose development is not lucrative under the present regime. But in the medium term, the HIF will likely attract high-impact medicines for global diseases and conditions: those that will make a great difference to the health of rich and poor alike.

Patents create monopoly power, which enables the patentee to push prices up as long as the loss in profits from lost sales is smaller than the increase in profits from

higher prices. Given the enormous disparities in incomes within and across countries, this means that profit-maximizing companies, to meet their obligations to shareholders, must deny access to life-saving medicines to many. This is a hard decision; but if the HIF were created, no one would have to make such a choice. Firms could then *increase* their profits by selling their medicine everywhere at very low prices.

An attractive feature of the HIF is that this realignment of incentives needn't cost more. Wealthy people are already paying for pharmaceutical R&D through high prices for patented drugs, through high insurance premiums and through taxes to support national health systems. By reducing what consumers pay for registered drugs, the HIF offsets much of the cost it would impose on taxpayers for health impact rewards. Here the HIF takes advantage of the fact that allowing poor people to purchase a drug at marginal cost does not increase the cost to be borne by anyone else. The costs of R&D have to be covered somehow, but it is unacceptable to oblige firms to cover these costs through high prices that will lead people to die. The HIF offers a workable, practical solution to this important moral dilemma.

HOW THE HEALTH IMPACT FUND WOULD WORK

This section briefly describes how the HIF would work. A more comprehensive account is given in *The Health Impact Fund: Making New Medicines Accessible for All*.[3]

Granting Payments

The Health Impact Fund would have a fixed pool of money to pay out annually. Each year, this amount would be disbursed, and each firm would receive a share of the pool equal to the share of assessed health impact of its registered medicines. When assessing health impact, the HIF would essentially estimate the difference between (1) the actual health status of people who consumed the registered product and (2) the estimated health status of these people, had they not had access to the registered product or to any other products introduced less than two years before the registered product. (The HIF would also take into account effects due to decreased transmission of communicable diseases.) The HIF thus will estimate the incremental health impact of each registered product, relative to the standard of treatment two years before the product became available. Such an estimate will be performed annually, and each registered product will be rewarded, on the basis of its assessed health impact, for ten years. If agreed by the funding partners, the size of the reward pool could be expanded automatically in any year in which the reward rate falls below a predetermined floor.

To be eligible to register a product under the HIF reward scheme, a firm would have to obtain market approval from one or more significant regulatory authorities, for a new product or a new use of an existing product. It could then register its product or new use with the HIF and would then be rewarded on the basis of the product's global health impact in its first ten years following marketing approval, or on the assessed health impact of the new use of the product for five years. To register a product with the HIF the company would be required to:

- make a good faith effort to obtain marketing approval or approval of the new use wherever the product is needed;

[3] This submission reflects several changes from the book, and we are engaged in consultations to further refine the proposal.

- pre-authorize the HIF to seek marketing approval for the product wherever the registrant had failed to do so and to subtract the cost of this effort from the registrant's next health impact reward payments;
- sell the product at a low price, no higher than the long-run marginal cost of production and distribution as determined by the HIF, or enable generic competition, wherever the product is legal and needed;[4]
- pre-authorize the HIF to sub-license the relevant patents to generic firms who would supply it wherever the registrant fails to provide an adequate supply;
- provide sales data and other evidence required by the HIF for assessing the product's global health impact during the reward period;
- pay an annual fee calculated to cover the costs of health impact assessment;
- pre-authorize the HIF so that it can, following the end of the reward period, sublicense to generic firms the patents needed to manufacture and market the product.

A company could seek pre-registration clearance from the HIF to ensure that its product was suitable for HIF registration. Some products might be unsuitable—for example, if drug "X" were about to become generically available, the HIF would not want to allow registration of a close substitute whose health impact would be assessed against a baseline in which X is included at its current high price. The HIF would issue rules clarifying the circumstances in which it might reject registration of a new product or new use and would reserve the sole right to apply these rules.

Assessing Health Impact

The HIF would have to use a single measure for assessing the health impact of each registered product. The standard measure of health impact is the Quality-Adjusted Life Year, or QALY.[5] A drug that extended a person's life by ten healthy years would be credited with ten QALYs. The health impact of a medicine will be considered to have occurred at the time the medicine was consumed; so the entire ten years of extra life would be rewarded even if some of these years fell beyond the end of the medicine's specific reward period. Health impact would be evaluated without regard to wealth or income, and aggregated globally, to assess a drug's total health impact in each year.

Estimating QALYs is difficult, and it would take a great deal of data to make such evaluations credible. The essence of the assessment process involves obtaining evidence on the incremental effect on health of the average consumer of the registered product. When this product merely displaces some existing medicine, the analysis is relatively straightforward. But typically a medicine's QALY impact would be more complex,

[4] We see three possible mechanisms to address the need to obtain low prices: (a) requiring open licensing of all relevant intellectual property, data, and know-how to enable generic competition; (b) requiring similar licensing with the provision that generic manufacturers would supply the registrant, who would then be obliged to sell the registered product at the purchase price; or (c) not requiring any kind of licensing, but ensuring low prices through setting a price ceiling equal to the estimated average cost of production. We are in the process of evaluating these three approaches and possible combinations.

[5] Alternative measures with similar properties include "Disability-Adjusted Life-Years" (DALYs), Healthy Year Equivalents and Saved-Young-Life Equivalents. For discussion of these options, see Drummond, Michael F., Mark J. Sculpher, George W. Torrance, Bernie J. O'Brien, and Greg L. Stoddart. 2005. *Methods for the Economic Evaluation of Health Care Programmes*. 3rd ed. Oxford: Oxford University Press.

arising from an improved therapeutic profile, from increased use due to a lower price, and from more effective use due to better prescription and patient instruction practices.

Assessments would be based not only on information commonly available today. Because health impact would be assessed on a global scale, for a variety of types of medicines, a variety of tools would have to be used. Manufacturers would be obliged to submit information about the distribution of their product, or to require distributors to submit such information to the HIF, so that the amount of information about how drugs were being distributed would increase substantially. Stratified sampling could be used to evaluate how drugs were actually being used, and how effectively, in different countries. The data obtained in this way would be correlated with known global burden of disease measures as a further check. Data from "pragmatic trials" could be combined with data from clinical trials to obtain estimates of the difference between use in ideal settings and use in actual settings.[6]

The difficulty of rewarding innovators on the basis of assessed health impact is significant, but the alternative is to reward innovators on the basis of ignorance. The current situation is that insurers—state or private—determine access to drugs for most people in developed countries. They list drugs on their formularies only after doing some kind of assessment regarding the drug's effectiveness and comparing that to its price. The HIF thus requires a judgment to be made on cost-effectiveness similar to that commonly made by insurers today. An important difference is that while most insurers today make their listing decision based on preliminary information from clinical trials about the product's effectiveness, the HIF will rely on data derived from the actual use of the product.[7] In addition, unlike most insurers, its payments are intended to be conditional on incremental improvement over alternatives. (Most insurers list new drugs on the formulary if they are no less effective and no more expensive than other similar products.) Those products which achieve substantial increases in effectiveness will be most generously rewarded by the fund.

The HIF would need a substantial department devoted to continuously evaluating the health impacts of registered medicines. Such an assessment operation might require 10% of the fund, implying, given the proposed initial fund size of $6bn per year, an annual assessment budget of approximately $600m. This expenditure would improve incentives to innovators by ensuring that rewards track health impact. It would also generate valuable data that could be used by the medical profession to improve prescription decisions and by governments, international agencies, and NGOs for the promotion of health generally.

Funding

The HIF would require substantial government funding, including initial commitments of at least $6bn per year. (The net incremental cost to the partner countries would, however,

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[6] Roland, Martin and David J. Torgerson. 1998. Understanding controlled trials: What are pragmatic trials? BMJ 316: 285.

[7] Some insurers have successfully used "no-cure, no-pay" arrangements with drug manufacturers in which the payments to the manufacturer is conditional on the actual success of the product. This obviously requires monitoring similar to the assessment process of the HIF. (See, for example, Møldrup, Claus. 2005. No cure, no pay. *BMJ* 330: 1262–64; Hughes D., B. Tunnage, and S.T. Yeo. 2005. Drugs for exceptionally rare diseases: do they deserve special status for funding? *QJM* 98, no. 11: 829–36.)

be much lower because there would be substantial savings due to lower prices on new HIF-registered medicines.) Partner countries would have to commit to financial support for at least twelve years into the future at any time, so that innovators would have some assurance about the payments they could expect to receive. An ideal structure would involve countries committing a fixed share (perhaps 0.03 percent) of their annual gross national income, so that the HIF would grow in proportion to their economies. Such an approach would also ensure a kind of parity among the contributions of funding partners and lead to a larger scale of funding than any partner would achieve on its own.

To put the proposed size of the HIF in the context of annual expenditures on drugs, let us assume that countries representing one-third of global income agreed to underwrite the HIF.[8] On this assumption each country would need to contribute 0.03 percent of its gross national income (GNI) in order to reach the $6bn annual-pool target. For affluent countries with per capita income of around $40,000 per annum, committing 0.03 percent of GNI would constitute a contribution of $12 per citizen per year—as compared to average annual per capita expenditure on pharmaceuticals of $413 in the OECD countries (2005).[9] The net cost of the HIF to OECD citizens would be well below $12 because of the savings they would realize on HIF-registered drugs that, without the HIF, would cost much more.[10] These net costs are associated with substantial benefits. They would stimulate the development of widely accessible new medicines that reduce morbidity and premature mortality worldwide, would thereby improve global economic performance, and would also reduce dangers from otherwise neglected diseases.

Because the HIF would start out with very few registered medicines, the contributions of funding partners could rise to the target level over a three-year period. If a country decided to leave the system as a funding partner, its commitment would require it to continue to contribute over a period of years, albeit at a declining rate each year. This commitment would be necessary for the HIF to provide robust incentives for firms to undertake the long, risky, and expensive research efforts that can result in important new medicines.

Administration and Governance

The administrative structure of the HIF would consist of three main branches: the technical branch, the assessment branch, and the audit branch. The technical branch would determine standards for how health impact was to be assessed, so that there would be consistent expectations across countries and across diseases about data and how it would be interpreted. The assessment branch would apply those standards to the observed data and assess the health impact of each registered product. The audit branch would check the integrity of this process.

The Board of Directors of the HIF would bear ultimate responsibility for overseeing this process. As such, it would need to have the support of the funding

[8] This one-third target is very easily reached if the HIF is joined either by the United States or else by all or nearly all member states of the European Union.

[9] See Chart g5-4-01 of Organization for Economic Co-operation and Development. 2008. Health at a Glance 2007: OECD Indicators.

[10] It is difficult to know exactly how large the net cost would be, since this depends on which drugs are registered. To the extent that registered drugs have considerable sales in funding countries, there would be savings on drug prices reducing the net cost for funding countries. For some countries, the net cost could be negative.

partners, and so the composition of the Board would naturally include representatives of contributing countries, presumably with a voting representation reflecting their contribution share. It might also be suitable to include other stakeholders on the Board.

THE HEALTH IMPACT FUND: DIRECTIONS FOR PROGRESS

The Health Impact Fund offers an integrated, evidence-based mechanism for improving pharmaceutical innovation and access to new medicines while addressing along the way other important issues in pharmaceutical markets such as neglected diseases, counterfeiting, and the "last mile" problem of drug distribution.

The HIF proposal is in many respects similar to the "Priority Medicines and Vaccines Prize Fund" proposal made by Barbados and Bolivia, though with some minor differences. We have tried to flesh out the proposal to provide a sense of how such a fund could work, since the difficulty of implementing such schemes rests substantially in the details. We are currently working on various aspects of the proposal: (1) developing a stronger base of evidence on the operation of health impact evaluation; (2) examining legal issues arising from the possible implementation of the fund; (3) considering the optimal design of the reward and pricing mechanism; and (4) consulting with a variety of stakeholders and experts. While there are substantial and important issues which need further consultation and possible refinement, we believe that the proposal is promising and deserving of serious consideration.

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