

**Submission of *Incentives for Global Health* to the Secretary-General's High-Level Panel on Access to Medicines**

## **The Health Impact Fund (HIF)**

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### **Abstract**

We propose the Health Impact Fund (HIF) as a new way to incentivize and pay for pharmaceutical innovation. The HIF is meant to address the inherent deficiencies of the existing patent monopoly system for pharmaceuticals by providing a complementary, pay-for-performance mechanism. By more closely aligning the economic incentives for innovators with global public health needs, the HIF aims to draw to market badly needed health technologies that are not sufficiently profitable under TRIPS. Pharmaceutical innovators worldwide would have the *option* of registering new medicines with the HIF. By registering, an innovator would agree to provide its drug at or below cost anywhere it is needed and, in exchange for foregoing normal sales profits, would be rewarded based on the HIF's assessment of the drug's health impact. The HIF would have a fixed pool of money to pay out annually. Every year, any HIF-registered product would receive a share of the pool equal to its share of the health impact achieved by all registered products. The HIF would be an international fund, financed by willing governments according to national income. The costs to governments and taxpayers would be largely offset by lower prices on drug purchases and insurance premiums.

The HIF model has been refined over ten years, incorporating important contributions from prominent members of government, industry and civil society. It is now ready to be tested experimentally. Owing to the financial and technical ambition of the HIF, we propose a smaller pilot (the "miniHIF") to demonstrate feasibility as well as to illuminate potential challenges. The miniHIF would be a time-limited competition among several pharmaceutical innovators willing to register new health technologies, with rewards allocated on the basis of measured health impact.

## **Introduction**

The proposed Health Impact Fund would be a permanent mechanism to support biopharmaceutical innovation. By registering a new product with the HIF with the commitment to make it widely available at cost, any pharmaceutical innovator would become entitled to participate in HIF reward payments. Funded mainly by willing governments, the HIF would distribute fixed annual reward pools. Each annual pool would be divided according among the registered products according to the health gains each product had achieved in the relevant year, with products eligible to receive payments for ten years.

The HIF is designed to address three critical failings in our current system.

First, it would help address the significant gap in incentives for innovation in pharmaceuticals. In particular, the HIF would create effective rewards for innovators that invest in therapeutically important innovations that are commercially unattractive in our current system. For example, diseases concentrated among the poor, for which the commercial returns are too small to justify investment in needed therapies, could become attractive targets given the existence of the HIF.

Second, the price of HIF-registered drugs would be capped at the cost of manufacture and distribution. Registered medicines would therefore have much greater reach, especially among poorer patients, than has been typical for high-priced modern drugs.

Third, the HIF is designed so that the registrant has an incentive to ensure that the product is available. Many schemes that rely on low prices alone to enable wide distribution do not create a commercial incentive to extend availability to poor people in remote areas, since there is no profit in selling low-margin products to them. The HIF, by making rewards dependent on health impact, will make it profitable for innovators to invest in reaching poor, rural patients. These incentives would stimulate innovators to make greater efforts to collaborate with local health authorities and clinics, and to increase investment in distribution.

Collectively, these changes to the way important drugs are developed, priced, and distributed would have substantial impacts on public health.

## **Technical feasibility**

The key technical challenge for the HIF is to develop a system of health impact measurement. Such a system needs to be cost-effective, credible, and, as much as possible, consistent across diseases and countries. While the specific assessment plans to be worked into the various registration contracts must take account of each medicine's specific characteristics, such variations must be grounded in a coherent overall framework for the fair and efficient assessment of health gains.

Although the idea of basing rewards on health impact sounds ambitious, the HIF would operate much like many national insurance systems, such as the UK's NHS. In the NHS, reimbursed prices are typically related to expected health impact, where the analysis of health

impact is based on clinical trial data. The HIF could do the same: estimate health impact on the basis of pre-approval clinical trials. Of course, it would be attractive to improve on this to the extent that it was feasible and cost-effective to collect additional post-marketing information. There has been a substantial growth in pay-for-performance pricing schemes in recent years, with many products, for example, offering money-back guarantees if the patient does not respond (Garrison 2013).

Many countries do not have the administrative structures in place to facilitate data collection. We therefore anticipate that the HIF may spend up to 10% of its total budget on the assessment process. While costly, the assessments would yield much data with independent clinical value, data that could be shared with local health authorities to improve the delivery of health care. We also anticipate that the incentive associated with registration would encourage innovators wishing to register drugs with the HIF to design clinical trials that enable clearer assessment of the incremental health impact of the drugs. The same incentive would encourage innovators to collect information demonstrating product effectiveness, further supplementing the data available to the HIF.

The miniHIF discussed below would serve as an excellent test of the technical feasibility of the HIF.

## **Financial feasibility**

### Funding

We have estimated that the optimal minimum efficient scale for the HIF is roughly \$6bn per year – enough to sustain meaningful rewards for approximately 20 new drugs at a time. The HIF would therefore depend on substantial annual funding from governments/taxpayers. However, the HIF would also create commensurate savings through lower prices for registered products, since all products must be sold at a low price during the reward period. That is, although the proposed annual rewards sound imposing, the net cost to taxpayers would be much less and could even be negative. *The main effect of the HIF is to reorganize the way we pay for some medicines*, rather than to increase the amount of funding for them. Since current global pharmaceutical expenditures are approaching \$1 trillion, the proposed scale of the HIF would represent a small fraction of the market.

### Cost-effectiveness

The HIF can be seen as the logical extension of the move towards value-based pricing by national drug insurers. There are a number of ways in which the HIF is particularly well suited to delivering a cost-effective solution.

First, the HIF is designed so that it pays only for success. There are no payments if a product is not ultimately developed; no payment if a product is developed but not appropriately used; and no payment if a product is developed, delivered, appropriately used but no better than the therapy it replaces.

Second, the HIF is designed so that registered drugs are cost-effective. Any drug that can generate more profits outside the HIF will not be registered. But that means that the cost to payers per unit of health impact must be lower for products registered in the HIF. In other

words, registered products will have a lower cost-benefit ratio than those that are not registered.

Third, the HIF is cost-effective in that it creates competition among drugs of different therapeutic classes for the same stream of rewards. This means that payers don't spend too much in one area while starving others because of political decisions about trying to target "fashionable" diseases rather than those that can most effectively be addressed.

Fourth, the HIF is cost-effective in that it doesn't constrain the ways that innovators can generate health benefits. Not only are there no constraints on therapeutic class, there are no artificial constraints on the (legal) activities innovators can engage in. For example, an innovator might earn profits by focusing on developing a better product; or it might earn profits by investing more heavily in distribution or in price-cutting to increase sales to marginal populations. The HIF doesn't favor any one of these activities over any other. Instead, it enables innovators to do whatever will most cost-effectively deliver health impact through new pharmaceuticals.

Finally, the HIF is cost-effective because it would create incentives to invest exactly in the areas that are most underserved. The least appealing investments, today, of course, are those for which potential payers are poor and unable to pay high prices. The HIF would therefore target exactly those investments with the best mix of likely health gains and smallest profitability under the current system.

### **Intellectual property management issues**

The HIF is designed to complement existing intellectual property systems. It leaves unaltered the patent system and addresses any deficiencies by creating an alternative payment system

One of the key HIF design issues is to specify the contractual requirement that will ensure that registered drugs are available at low prices. Possible models include open licensing of registered drugs, as in the Medicines Patent Pool; tendering production by a small number of generic manufacturers; or price regulation based on estimated cost (Hollis 2009). The optimal design will likely depend on the individual drug, given variation in the competitiveness of manufacturers in different drug markets and the distribution systems. In all cases the innovator would retain IP, but would be required to give up certain rights in exchange for HIF rewards. In all cases, at the end of the reward period, the innovator would be required to offer open licenses for production of the registered product.

### **De-linking**

The HIF is a "de-linking" proposal since it separates the reward for innovation from the price (Love and Hubbard 2007). This kind of approach has several benefits. First, it enables low prices for registered products, to enhance access. Second, it improves incentives for innovation for products having high therapeutic value, but poor commercial prospects. Third, it increases the incentives for innovators to supply products even when prices are low, thus increasing availability.

## **Equity**

Two key principles of the HIF relate to equity and distribution. The first is that all human lives should be valued equally, regardless of ability to pay or other factors. The second is that the distribution of the cost of innovation among countries should be progressive, and thus based on income rather than need.

## **Accountability**

The HIF must generate reliable and high quality health impact data in order to fairly allocate rewards among registered medicines. Innovators will be competing to obtain rewards, and this competition for fixed annual pools ensures that the HIF has to be responsive and will be accountable to the registrants for having a fair process. At the same time, governments that are funding the HIF will be interested in knowing that their contributions are being used appropriately. Therefore, the HIF must be explicitly accountable both to governments and to participating innovators, and have their confidence in executing its role in a fair and independent manner

Preliminary proposals for governance of the HIF are described in Chapter 4 of Hollis and Pogge (2008). The board would likely be composed of contributing countries, representatives of agencies with a public health interest such as the WHO, and representatives of NGOs and patient groups. The internal organization could consist of a technical branch, which would establish general rules for assessing health impact; an assessment branch, which would apply those rules to determine the health impact of individual products; an audit branch; and support branches for finance, IT, and human resources.

## **Synergy with Product-Development Partnerships (PDPs)**

The HIF is structured to work with other mechanisms such as PDPs and open source science. The HIF offers three key benefits to PDPs. First, if the PDP were structured so that the product is required to be registered with the HIF, then there would be a mechanism to control price. Second, despite the pricing limitations, there would be commercial incentives to increase availability of the product in developing countries. Third, the HIF would create a funding system for successful PDPs: they could presumably share rewards with the commercial partner, and these rewards would in turn provide ongoing funding to the public partner. See Hollis and Pogge (2010).

## **Piloting the HIF: miniHIF**

A frequent comment on the HIF is that it is an ambitious project that needs to be tested out at a smaller scale. There are already many tests of pay-for-performance mechanisms being used in pharmaceutical markets. However, it would be helpful to see a *competitive* pay-for-performance arrangement mainly in low- and middle-income countries. We therefore propose the “miniHIF”.

The miniHIF would be a competition for pharmaceutical firms and PDPs to achieve health impact through an innovative drug, vaccine, delivery mechanism or formulation used mainly in low- and middle-income countries (a “project”). Pharmaceutical innovators would be invited to bid through a Request for Proposals; successful proposals would become eligible for rewards based on health impact achieved through the initiative. Proposals would be screened on the basis of expected health impact; a commitment to extending access to poorer populations; and measurability.

The available reward pool would be divided among the accepted projects in proportion to the health impact achieved by each during a defined period of time (e.g. 3 years). The miniHIF could be structured to operate within an existing institution, in the same way, for example that the AMFm was managed by the Global Fund.

We propose the miniHIF to be funded in the range of \$60m - \$200m; a larger amount would allow more proposals to be funded, and would draw in more ambitious proposals. The amount must be sufficient to pay for the administration of the competition, as well as the assessment of health impact. The Institute for Health Metrics and Evaluation has agreed in principle to perform the assessment function for the miniHIF. The average amount awarded per proposal should be enough to attract serious proposals, i.e. at least \$25m.

Starting from the miniHIF, it would be possible to increase the scale of pilots, ultimately concluding in a fully competitive, permanent HIF.

For more details on the miniHIF, please see <http://healthimpactfund.org/wp-content/uploads/2016/02/mini-HIF-proposal-2016-Feb.pdf>

## **Evidence**

1. A key piece of evidence in favor of the HIF approach is the explosive growth in cost-effectiveness and comparative-effectiveness studies and the use of such data by national insurers. While the HIF would not engage in cost-effectiveness analysis, it would engage in effectiveness analysis. More recently there is an increasing use of performance-based reimbursement agreements between pharmaceutical manufacturers and insurers. The rapid growth in this approach indicates that it is a useful tool and that it has validity in practice.
2. A second key piece of evidence is that there are gaps in the set of innovative drugs that are commercially attractive. While PDPs are effectively addressing some of those needs, areas of need remain. (See, Moran et al 2011, p. 85.) The HIF would rely on the ingenuity of pharmaceutical innovators to identify and take full advantage

of the most compelling opportunities for realizing cost-effective health gains.

3. Price remains an important barrier to access to drugs, even given price discrimination and donation programs. (See, e.g. Chauduri et al 2003 and Saul 2008 for examples in very different settings). Part of the problem is high retail mark-ups that are not effectively controlled by suppliers. (See, e.g. WHO 2008).
4. Even aside from issues of price, availability is sometimes an important barrier when there are inadequate commercial incentives to ensure effective supply (See, WHO 2006, p. 99). Barriers to availability may include inadequate diagnostic resources (including health care personnel) and incomplete distribution systems. (See, e.g. Kotwani 2007). An appropriately motivated supplier could contribute to overcoming these barriers to availability.

## Summary

**Impact on policy coherence:** The HIF offers a mechanism that recognizes (1) the central role of the pharmaceutical industry in developing and bringing new medicines to market within our existing system of intellectual property; (2) the importance of price as a condition for access; and (3) the importance of incentives for improving human health through medicines. The HIF would reward pharmaceutical innovators according to how well they serve public health goals.

**Impact on public health:** The HIF, by design, would create incentives to expand the set of medicines, by creating commercial incentives where none now exist and spurring need-based pharmaceutical innovations. In addition, by delinking price from the reward for innovation, the HIF would enable wider access of essential drugs to those in need.

**Advancing human rights:** The fundamental feature of the HIF is that all lives are valued equally, regardless of ability to pay. As such, the HIF offers a practical way of realizing the human right to health.

**Implementation:** The HIF is an ambitious proposal. The miniHIF offers a path to test the feasibility and effectiveness of this system of competitive rewards based on actual health impact. It would also offer a starting point for countries to work together to fund this first-of-its-kind project.

## Expressions of Support

### Janssen Pharmaceuticals (letter, Aug 12 2015)

“The purpose of this letter is to express the support of Janssen, the Pharmaceutical Companies of Johnson & Johnson, for the proposed Health Impact Fund and miniHIF. ...

“With sufficient funding, the HIF could be an effective way of stimulating investment from small and large bio-pharmaceutical companies to address the needs of low-income populations. It would align commercial incentives with social goals of reducing excess morbidity and mortality. It could support companies, including Janssen, in their efforts to develop innovative products within a competitive, market-based framework that rewards outcomes.

“It would be sensible to test the viability of the HIF approach at a smaller scale. A timelimited ‘miniHIF’ could demonstrate the responsiveness of firms to competitive performance-based rewards, and could provide a live example of measuring performance in challenging environments.

...

“We hope to see the miniHIF funded, and would certainly make an effort to participate. We will also be pleased to provide our views on the structure and design details of the miniHIF and to help propagate the project among our peers within industry associations and beyond.”

### German Social Democratic Party, [Motion](#) (16 June 2010)

“The German Bundestag calls on the Federal Government ... to actively support the pilot phase of the HIF under the auspices of the Global Fund, and to financially and actively support and promote the establishment of a HIF, tested through evidenced efficacy.”

Renewed with [Bilateral Support in the Bundestag](#), 19 May 2015

### [Liberal \(Venstre\) Party of Norway](#) (June 2015)

An international Health Impact Fund (HIF) should be established as a supplement to the current patent system. Through HIF pharmaceutical companies can voluntarily register their drugs and commit to making them available at the lowest price against payment of support over ten years from the Fund on the basis of major health impact their drugs have. This gives companies incentives to develop medicines for those with the greatest health needs and not only those with the greatest purchasing power.



## References

- Chaudhuri S, Goldberg P, Jia P, 2003. Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India. NBER Working Paper No. W10159, December.
- Garrison, Louis P., Adrian Towse, Andrew Briggs, Gerard de Pouvourville, Jens Grueger, Penny E. Mohr, JL Hans Severens, Paolo Siviero, and Miguel Sleeper. "Performance-based risk-sharing arrangements—good practices for design, implementation, and evaluation: report of the ISPOR good practices for performance-based risk-sharing arrangements task force." *Value in Health* 16, no. 5 (2013): 703-719.
- Hollis A, 2009. The Health Impact Fund and Price Determination. Incentives for Global Health Discussion Paper #1, available at [http://healthimpactfund.org/wp-content/uploads/2015/12/DP1\\_Hollis.pdf](http://healthimpactfund.org/wp-content/uploads/2015/12/DP1_Hollis.pdf)
- Hollis A, Pogge T, 2010. Product-Development Partnerships and the Health Impact Fund. Incentives for Global Health Discussion Paper #9, available at [http://healthimpactfund.org/wp-content/uploads/2015/12/DP9\\_Hollis-Pogge\\_PDPs.pdf](http://healthimpactfund.org/wp-content/uploads/2015/12/DP9_Hollis-Pogge_PDPs.pdf)
- Kotwani A et al, 2007. Prices & availability of common medicines at six sites in India using a standard methodology. *Indian Journal of Medical Research* 125: 645-654.
- Love, James, and Tim Hubbard. "The Big Idea: Prizes to Stimulate R&D for New Medicines." *Chicago-Kent Law Review* 82 (2007): 1519.
- Moran M et al, 2011. Neglected disease research and development: Is the global financial crisis changing R&D? Policy Cures G-Finder report for 2010.
- Saul S, 2008. In Sour Economy, Some Scale Back on Medications. *New York Times*, October 21: A1.
- WHO, 2006. Report of the Commission on Intellectual Property Rights, Innovation and Public Health.
- WHO, 2008. "Medicine Prices in Kenya" available at [http://www.who.int/medicines/areas/technical\\_cooperation/MedicinepricesKenya.pdf](http://www.who.int/medicines/areas/technical_cooperation/MedicinepricesKenya.pdf)

## A Bibliography of the HIF

*For more on the HIF generally, see*

Hollis A, Pogge T, 2008. The Health Impact Fund: Making New Medicines Accessible for All. Incentives for Global Health.

*Extensive materials on the HIF are available at*

The HIF website: [www.healthimpactfund.org](http://www.healthimpactfund.org)

*For a **short summary** of the HIF proposal, see*

Banerjee A, Hollis A, Pogge T, 2010. The health impact fund. *Lancet*. 375(9727):1693

*For a discussion of how the HIF might be used to assist in the development of **antibiotics**, see*

Outterson K, Pogge T, Hollis A, 2011. Combating antibiotic resistance through the Health Impact Fund. In Glenn Cohen, ed. *The Globalization of Healthcare*. Oxford University Press

2012.

*For a discussion of the **ethical foundations** of the HIF approach, see*

Pogge T, 2009. The Health Impact Fund and Its Justification by Appeal to Human Rights. *Journal of Social Philosophy* 40, no. 4, 542–569.

*For **independent analyses** of the HIF, see*

Amisano F, Cassone A, 2011. Economic sustainability of an alternative form of incentives to pharmaceutical innovation. POLIS Working Papers n. 181.

Grootendorst P, 2009. How Should We Support Pharmaceutical Innovation? *Expert. Rev. Pharmacoeconomics Outcomes Res.* 9(4): 313-320.

Lexchin J, 2010. One step forward, one step sideways? Expanding research capacity for neglected diseases. *BMC International Health and Human Rights* 10:20.

Longo, CJ, 2011. Encouraging pharmaceutical innovation to meet the needs of both developed and developing countries. *International Journal of Development Issues*, 10(1): 92-101.

Pekarsky B, 2010. Should Financial Incentives be Used to Differentially Reward ‘Me-Too’ and Innovative Drugs? *Pharmacoeconomics* 28(1): 1-17.

Rubio JC, 2015. Ebola, R&D on Neglected Diseases and the Health Impact Fund. <http://ssrn.com/abstract=2663616>.

Timmermann C. 2012. "The Health Impact Fund and the right to participate in the advancement of science." *European journal of applied ethics* 1, no. 1 (2012).

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