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Incentives for Global Health

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The Health Impact Fund: Creation and Commitment*

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Abstract: This note outlines a process designed to lead to the creation of the Health Impact Fund and the making of initial contributions and longer-term commitments for its start-up and operation. Stage 1 involves an initial meeting of funders to establish the path leading to establishment of the Fund. Stage 2 consists of a series of meetings, culminating in substantial agreement on all key points for the Fund's establishment, operation, and financing. In Stage 3, a Memorandum of Understanding concerning all understandings for the operation and financing of the Health Impact Fund is drafted by the HIF Secretariat and agreed upon by the funders. Finally, in Stage 4, the HIF commences operation.

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INTRODUCTION

The proposed Health Impact Fund (“HIF” or “the Fund”) has been gathering increasing momentum. Countries, international organizations, foundations, non-governmental organizations, pharmaceutical and other firms, and the academic community have engaged with Incentives for Global Health (“IGH”) to learn more about the HIF and to explore how the proposal can be refined and brought closer to realization. Some have provided tangible assistance. In December 2009 the World Health Organization’s Expert Working Group on Research and Development Financing endorsed the HIF as a promising financing tool to stimulate research and development for affordable medicines.

One of the requirements for HIF to realize this promise is a clear understanding of the mechanisms that will allow potential funders to convert their expressions of interest in the HIF into binding commitments. To this end, this note outlines a process designed to lead to the creation of the HIF and the making of initial contributions and longer-term commitments for its start-up and operation.

States are expected to be the principal funders of the HIF. Consequently, any process for creation of the Fund and the making of financial contributions and commitments has to be grounded in the special requirements of sovereign decision-making. This means that the process must accommodate states’ internal processes for committing budgetary resources and for spending them. Laws may need to be passed and prerequisites for action by the executive branch need to be observed. Representatives must have the opportunity to brief their authorities and to receive instructions. All this takes time. The process for moving toward the creation and financing of the HIF must be respectful of this complex reality.

Further, the process must also be such that it leads to coordinated action at the end: when the HIF opens its doors, a certain minimum of the resources necessary for operation must be available and receipt of the remaining funds must be assured. All participating countries and other funders must have had the time and flexibility they need to be able to commit themselves effectively by that moment.

The process sketched out below seeks to meet the above requirements. It is broadly based upon the mechanism used successfully for nearly 50 years by the World

Bank for the replenishment of the resources of the International Development Association (“IDA”), its soft-loan affiliate, and later followed, for example, by the Global Fund to Fight AIDS, Tuberculosis and Malaria (“Global Fund”). There have been variations and adaptations over time and according to circumstance, but the essence of the process has proved durable and productive. It has enabled the Global Fund to obtain pledges of nearly US\$10 billion for its second replenishment in September 2007, while just a few months later, in December 2007, IDA concluded its fifteenth replenishment exercise with binding commitments from members for US\$21.1 billion and with agreement on key policy and operational concerns.

While the IDA and Global Fund processes are used cyclically (every three years) and can be deemed a feature of the long-term funding arrangement for these institutions, it should be pointed out that the process laid out below is intended only to lead to the creation of, and the initial contributions and commitments to, the HIF. The process for ensuring continued funding of the HIF, i.e. beyond creation and initial commitment, is one of the matters that will need to be discussed and agreed upon by the original funders during the process outlined below.

The HIF is, essentially, a prize fund that rewards pharmaceutical innovation in proportion to the share of health impact of the registered new product out of all products registered with the HIF. The purpose, justification, and basic operations of the Fund are detailed in *The Health Impact Fund: Making New Medicines Accessible for All* (Incentives for Global Health, 2008, available at www.healthimpactfund.org). That document, hereafter referred to as “the HIF book”, serves as the background for this process proposal.

While states are expected to be the primary contributors, the HIF will actively solicit contributions from international organizations and foundations. Not all funders may wish to commit themselves to assured long-term funding but may find it more appropriate to make occasional contributions. When it is necessary to distinguish between those funders who commit themselves to regular funding and those who make ad hoc contributions, the former will be referred to as “Partners” and the latter as “Contributors.”

The process described below thus offers a roadmap for how the international community can bring the HIF into being. This process is likely to require the establishment of a greater degree of consensus internationally about the HIF than exists

currently, including a clear sense of how it would operate. This will require further exploration of the HIF proposal by experts in a variety of fields. The process described below will have to follow, and be informed by, that exploration.

THE PROPOSED PROCESS

Stage 1: the initial funders meeting

All potential Partners and Contributors are brought together for an initial funders meeting. The purpose of the initial meeting is fourfold:

- (a) to collect the potential funders' views on the scope, modalities, governance, and financing of the HIF;
- (b) to consider a proposal for the legal incorporation/organization of the HIF;
- (c) to obtain the potential funders' agreement to a process leading to the establishment of the HIF and the securing of binding financing commitments; and
- (d) to afford an opportunity to the potential funders to indicate other matters that they deem necessary to be addressed in the preparation for, and establishment and operation of, the HIF, and to agree on the priority with which these others matters should be addressed.

Incentives for Global Health ("IGH") will organize the initial funders meeting and will serve as secretariat for the meeting, with the assistance of the hosting country or organization. When acting as the secretariat for the initial and subsequent meetings of the funders, IGH will be referred to as "the Secretariat."

The Chair of the meeting could be the designated representative of a potential funder country that volunteers to host the meeting. This would be a visible signal of the host country's serious interest in the HIF, would assure that the country would have an important voice in shaping the further process for the creation of the HIF, and would provide a proper channel for the invitation of other countries' official representatives.

Alternatively, the initial funders meeting could be hosted by an international organization with a direct interest in the creation of the HIF on suitable terms and conditions, such as WHO or the Global Fund. Such a venue would have the advantages of being able to utilize the existing arrangements for countries' participation in the work of that organization and the involvement of expert staff. The Chair of the meeting would then be a member of the senior management of the hosting organization.

It is possible to entrust the chairmanship of the initial (and subsequent) meetings to a person of high international stature as was done, for example, by the Global Fund during its Second Replenishment exercise.¹ The involvement and experience on the international stage of such a figure would lend appeal to the HIF, would attract attention to the initial meeting, and would help ensure a smooth and high-calibre discussion. However, at this stage, it would appear that the goal of assuring countries', or an international organization's, close cooperation in the creation of the HIF would be best served by allocating the chairmanship of the initial and subsequent meetings accordingly.

Potential funders may send such number of staff to the initial meeting as they wish; however, they would be requested to appoint one person to be authorized to speak on its behalf. A written statement of that authorization should be placed on record with the Secretariat. The authorized representatives of the potential funders will be referred to collectively as "the Representatives."

The questions of who or what ministry or department within a donor should be the proper authorizing party may be resolved differently by different donors. For countries, such as Norway, that have espoused a foreign policy explicitly informed by the need for improved health equity in the world, the Representative could come from the Foreign Ministry. Other countries may wish their Representative to be instructed by its foreign aid department or public health ministry. When the time comes for making binding financial commitments, the Representative may need to come from the country's Treasury or Central Bank. It is not indispensable that the authorized spokesperson be the same at all preparatory meetings. It would, however, be highly desirable that a core of participants from all potential funders be the same in successive

¹ Meetings for the second replenishment of the resources of the Global Fund have been chaired by Kofi Annan, former Secretary-General of the United Nations, and Sven Sandstrom, former Managing Director of the World Bank.

meetings so as to enhance prospects for a common endeavor and for mutual understanding and collegiality during the deliberations.

IGH would have to be in a position to ensure that competent staff would be available to answer questions with respect to strategic and technical matters regarding the HIF or, indeed, with respect to any matter that Representatives may wish to raise.

An important subject to be dealt with during the initial meeting is the legal organization of the HIF. The manner in which this matter is resolved will have determinative consequences for the further preparatory activities and for the operation and financing of the Fund. As currently envisioned, the HIF could be established as a new international organization with suitable privileges and immunities, a not-for-profit foundation established under the laws of a host country, or as a separate program of an existing international organization. In order to facilitate consideration of these alternatives, IGH should prepare or commission a paper explicitly examining the advantages and disadvantages of these different organizational forms.

IGH will propose that the process leading up to the establishment, operation, and financing of the HIF be substantially the same as laid out in this note. Representatives will, of course, be free to offer modifications or to suggest altogether different ways of proceeding. It is important, though, that the Representatives come to agreement during the initial meeting on the process they wish to see followed for the launching of the HIF.

At the end of the initial meeting, the Chair, with the assistance of the Secretariat, shall submit a "Chair's Summary", noting in particular all agreements reached, items selected for further discussion, and the priority with which such items should be addressed.

Stage 2: the subsequent meeting process

The second stage consists of a series of meetings of the potential funders to discuss and come to a consensus on all key matters for the establishment, financing, and initial operation of the HIF. Essential topics to be discussed and agreed upon would include the size of the fund needed, burden sharing among the Partners, receipt of ad hoc contributions from Contributors, voting rights or other powers of decision-making to be attached to Partners' contributions, cooperation arrangements with technical agencies

(including a financial trustee and disbursing agent, hereafter referred to as the “Financial Agent”), a model agreement with registrants, a mechanism for the resolution of disputes between registrants and the HIF, rules for the resolution of issues that may arise among the Partners (e.g., failure to pay or early withdrawal), anticipated size and staffing of the organization, and all modalities for operation of the Fund.

The agenda for the second meeting should deal with a few matters that the funders deem of priority importance, as reflected the Chair’s Summary of the initial meeting. The Secretariat would likely prepare or commission papers necessary to deal with these matters. During the preparation of these materials, the Secretariat will informally consult with potential funders on the best way to forge consensus on the various views that may have been expressed on the topics in question, as well as with other interested parties, such as potential innovators, health experts, and the like. Consequently, the papers that will be discussed at the second meeting should, to the maximum extent possible, reflect the most likely basis for consensus.

Another potential Partner will be requested to host the second meeting and to appoint the Chair, unless agreement should have been reached during the initial meeting that an international organization would be the most appropriate host, in which case that organization would deputize a member of the senior management team to chair the meeting. The *modus operandi* of the second meeting would be the same as that of the initial meeting.

This process will be iterated until there is substantial agreement on all key points for the establishment, operation, and financing of the HIF. Thus, while several meetings will be necessary—there are only so many topics that can be properly dealt with in any one meeting (even a meeting that stretches out over a few days)—it is hoped that the papers will be sufficiently reflective of consensus and that the discussion during the meetings will be sufficiently robust so as to lead to close-to-final agreement within three or four meetings (including the initial meeting). Assuming three meetings for stage 2, and assuming a period of four months between meetings (three months for the preparatory papers and one month for internal consultation by the donors), the second stage would last 12 months.

The last meeting of Stage 2 will consider specific, detailed proposals for the establishment, operation, and financing of the HIF. The form of incorporation and organization selected for the HIF will necessarily indicate the kind of documentation

that will be required, such as draft articles of incorporation or international agreement, bylaws, matters related to recruitment and compensation of future staff of the HIF, and tax treatment of contributions to the HIF and staff compensation. Specific proposals for individual Partners' contributions and allocation of voting rights should be considered, as well as the treatment of financial resources to be received from Contributors. Payment procedures (modes, dates and currency of payment; encashment schedules if any) should be nailed down and there should be a basic agreement on the form of the instrument by which Partners will legally commit themselves to make their agreed upon contribution. Cooperation agreements with technical agencies and the Financial Agent should be substantially agreed upon.

Funders may also wish to consider a condition of effectiveness for the establishment of the HIF: to ensure that most Partner financing needed for continued operation will be effectively committed prior to the start of operations, they may specify that a substantial part of total commitments be received before the HIF starts operations.

Stage 3: end of the preparatory phase

This stage marks the end of the preparatory phase for the establishment of the HIF.

The Secretariat prepares a draft Memorandum of Understanding ("MOU") that details all matters on which agreement has been reached. If any items should still be unresolved, they are pointed out and a solution is proposed. The draft MOU contains certain key attachments: the final form of the instrument of commitment (or the requisite elements that must be included in Partners' instruments of commitment), the agreed upon individual Partner and Contributor contributions, the distribution of voting rights for Partners, and encashment schedules. Final drafts of all technical cooperation agreements and of the agreement with the Financial Agent are also attached.

To ensure that the HIF will be operational as soon as the effectiveness condition has been satisfied, certain matters will need to be dealt with in advance, such as legal fees for incorporation or other forms of formal establishment, rental of premises and equipment, and hiring of initial staff. Certain Partners and Contributors may wish to make funds available prior to their scheduled contributions to cover these expenses.

The draft MOU will specify how such advance payments are to be received and how the providers of these funds will be credited for these contributions.

A final meeting of the potential funders is convened at which all outstanding issues are resolved and all attached documents are approved.

The Chair's Summary of the last meeting appends the MOU as finally agreed upon. Since the final MOU will contain all understandings for the operation and financing of the HIF, it will need to be signed by all Partners and Contributors. Modalities for signature of the MOU should be agreed upon and a depository institution designated. The final form of the instrument of commitment should incorporate the final MOU by reference.

Stage 4: start-up

Stage 4 is the start-up phase.

All funders fulfill their internal requirements for signature of the MOU, for signature of the articles of incorporation or international agreement, and for deposit of their instrument of commitment. If the HIF should be established as a separate program of an existing international organization, that organization will specify any formal requirements that need to be fulfilled.

Advance payments are received by the Secretariat and used to carry out the legal procedures for establishment of the HIF, if established as a new legal entity, to rent office space and equipment, and to hire initial staff.

The legally established HIF, or the Financial Agent, receives instruments of commitment.

The HIF starts operations when the effectiveness condition has been met.