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Responsible governance in science and technology policy: Reflections from Europe, China and India

Arnaldi, Simone, Quaglio, GianLuca, Ladikas, Miltos, O'Kane, Hannah, Karapiperis, Theodoros, Srinivas, Krishna Ravi and Zhao, Yandong

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The Health Impact Fund; Issues and Challenges

Miltos Ladikas and Sachin Chatuverdi

Introduction

The Health Impact Fund (HIF) is an initiative that attempts to correct an overt imbalance in world affairs. It focuses on the issue of access to medicines that shows great discrepancies between the affluent and the poor people in the world. The relevant facts are well rehearsed by the World Health Organisation (e.g. WHO 2004b; 2006b):

- In 2004, some 970 million people (ca 15% of the world's population) were living below the extreme poverty line of $1 a day.
- About 31 percent of the world's population (ca two billion) lack access to crucial drugs.
- Worldwide, diseases related to poverty, including communicable, maternal, perinatal, and nutrition-related diseases, comprise over 50 percent of the burden of disease in low-income countries, nearly ten times their relative burden in developed countries.
- Currently, developing countries account for more than 80 percent of the world's population but for only around 10 percent of global pharmaceutical sales.
- Of the 1,556 new drugs approved for commercial sale from 1975–2004, only 18 (ca 1%) were for neglected tropical diseases.
- The top ten pharmaceutical firms account for ca 50% of global sales.
- Nine developed countries account for about 80% of global pharmaceutical sales.
- In 2006, just ten therapeutic classes of drugs accounted for 36% of global sales.

Such facts are many amongst other similar ones that show unequal distribution of access to basic amenities such as food and water, and great discrepancies in access to education, technology, energy, etc. The situation has been acknowledged as critical by the world governments that fifteen years ago instigated a series of coordinated actions under the name of the Millennium Goals. The Goals range from reducing hunger, to increasing access to health care, reduce child mortality, etc. Despite the good will and the good deeds that this initiative has brought about, it is clear that we are as far away as ever in realize these Goals at global scale. With the exception perhaps of mortality reduction, there is little else that the global community can show towards achieving the Goals it set for itself.

One might rightly wonder whether access to medicines is a top priority equivalent to the rest of the Millennium Goals. There is no easy answer to this. Medicines are essential for health and this in turn is essential for a fully

functioning individual, family or society. The arguments for focusing on medicines are therefore as good as for any other essential means of survival and improving one's lot but the solution is far from easy. The complexities that initiatives to increase access to medicines are faced with are formidable. They range from the incompatibility of current intellectual property rights legislation to the lack of political will and international structures to undertake such initiative.

HIF basics

HIF is a simple and elegant initiative that seeks to provide a solution to this issue. It was originally developed by Aidan Hollis and Thomas Pogge (Hollis & Pogge, 2009) as an interdisciplinary effort that encompasses economics, philosophy and governance at equal measures. Its concept is based on the basis of offering to reward any new medicine, on account of its global health impact. Pharmaceutical firms receiving marketing approval for a new medicines would be offered a choice between (a) exercising its usual patent rights through high prices or (b) registering its product with the HIF. Registration with HIF would require the firm to sell its product worldwide at a price near the average cost of production and distribution. In return, the firm would receive from the HIF a monetary reward based on the assessed global health impact of its drug. That makes HIF an optional pay-for-performance scheme for new pharmaceuticals that does not require amendments to the current patent protection processes.

The reward would be given every year from the HIF in proportion to their share of the health impact created by all eligible innovations. There are several designs possible for a reward mechanism. The HIF has a completely open approach to the possibility of various permutations and combinations under the framework of a reward structure that promotes innovation and access. The reward would be proportionate to the share of the health impact of registered products or firms, who would get a share of the fixed fund for ten years.

The reward disbursement to the registered firms with HIF at or before the time of marketing approvals for their drugs could be described as:

Payment = S x F

S= Estimated Health Impact of the product divided by the sum of estimated health impact of all the products eligible in that year.
F= Amount available from HIF for a particular year

HIF would issue royalty free production licenses in all jurisdictions against all patents required to manufacture and distribute the product thus, boosting generic competition. The key question before the HIF would be to select products which would be funded under the HIF scheme.The following criteria have been identified for the HIF eligibility of a product:

- New drugs patent protected in major patent offices with marketing

approvals.
- New approved indications for existing drugs when the new indication is patented.
- A drug soon to go off patent is not eligible for HIF support.
- Agreement to provide sales data after receiving HIF support
- Yearly registration fee to cover costs of health impact assessment.
- Assessment period for new products would be ten years and five years for new uses.
- HIF would set price range for products, which would be adjusted through inflation index.
- Ceiling on payments.

HIF is an elegant idea that attempts to solve an important global issue with the least disturbance of the status quo. In this chapter we will provide a sketch of the current state-of-art that HIF is developing within in terms of similar academic initiatives, the international patent regime, the main challenges it is faced with and finally, we will offer some thoughts of what the next steps for HIF should be in order to overcome the existing challenges.

HIF in the Current Academic Debate

HIF is naturally not the only initiative in dealing with the lack of access to essential medicines. The academic world has striven to understand the issues involved and find solutions to this problem for a considerable time already. Suggestions to overcome the limitations of the current IPR regime can be divided into four categories: those based on charity, compulsion, and push as well as pull mechanisms (Schroder & Singer, 2008).

Charity as a means to increase access to medicines is the most straightforward mechanism. It can take the form of a pharmaceutical company or an individual donating medicines directly to people in need. Drug donations are in existence since 1987 when Merck became the first company to donate a drug that treats river blindness (since then more than 25 million people had been treated with this donation). Many more firms have followed suit ever since but the results of the donation initiatives are limited. On one hand the drugs that are provided are for diseases that are not necessarily the most significant ones in the societies affected and on the other hand, there is evidence that they are of inferior quality or close to expiration dates. Moreover, donation is not a sustainable mechanism as it depends on the good will and the financial viability of the firms involved.

A similar charitable mechanism is that of differential pricing. It functions by pricing the same drug differently for different consumers according to affordability. Some firms have initiated differential pricing for anti-retrovial drugs with considerable success but this mechanism is also evidently non-sustainable. One problem is that different pricing increases fraud through re-importation of cheaper drugs to more affluent societies. An additional problem is that many countries set the pricing of drugs according to a “mean” global price

therefore, invariably decreasing the price of a drug that is offered cheaply in some parts of the world, making differential pricing unaffordable for many firms.

Another charitable mechanism is bulk buying of essential drugs by a charitable foundation that provides them free of charge to needy people. This has also been successful in some cases but it suffers from similar problems to the other charity mechanisms as it is unsustainable in the long term, depending on good will and not increasing availability since it only deals with existing drugs.

In terms of compulsion the most important mechanism is that of compulsory licensing that is described in the next section. Compulsory licensing is fraud with significant problems that make it the solution of last resort with dubious results. At the same time, as with charity, it targets accessibility and not availability. It might even hamper further the chances for drug innovation targeting poor people as it presents a possibility that the license will not be respected by states that are the main customers.

The mechanisms that target both accessibility and availability problems are the so-called push and pull types. The main push mechanism is that of publicly funded research. This is a direct undertaking that uses government funds to initiate innovation in drugs that in turn can be made available at very low prices to poor people. Since governments are non-for profit organisations, they are not obliged to recoup R&D costs and/or provide dividends to shareholders. Hence, drugs that are produced by public funds should be either freely available or at a price that recuperates the distribution costs only. Some governments are already undertake such initiatives and one can find specialised R&D programmes dedicated to innovation for orphan diseases or major developing world diseases such as malaria. Considerable amounts of money have already been spent with various levels of success. The main problem with such mechanism is that it cannot guarantee success since R&D is a hit-and-miss process with usually unpredictable results and it is also not viable in the long term as it requires perpetual spending of tax-payers money for a charitable cause. There are actually already signs that the current global financial crisis has hit publicly funded research of that type.

In terms of pull mechanisms, we find three main examples: priority review vouchers, advance market commitments and the Health Impact Fund. Priority review vouchers guarantee a speedy licensing process for drugs that are targeting poor people therefore increasing the return value of the drug for the company that need not count licensing processes in the innovation expenditure (apparently a considerable sum). But this does not necessarily result in more affordable drugs (the firm can still price it at will) and it is open to misuse by firms that might want to register a drug for other purposes and are not willing to eventually market it where it is most needed.

The advance market commitment offers a guarantee of purchase for specific drugs once they are licensed for use. The amount offered is high enough to create incentives for companies to fund innovation in the target drug type. This is an

elegant solution that avoids the pitfalls of many mechanisms and deals with both accessibility and availability issues. Its main drawback is the uncertainty of outcome and the possibility that a high reward for a specific type of drug could result in even less innovation in drugs that deal with similar poor-people's diseases.

Within the pull mechanisms, HIF offers a good alternative to existing practices. In its pay-as-you-go function based on actual health impact assessment it presents a way to promote innovation where it is mostly needed. A drug that is expensive to produce, targets a great number of patients but offers poor returns due to the income level of the target population, would be an ideal candidate for HIF. Without prejudicing the manner or direction of private R&D, or the established hard-won IPR system, it offers fair returns for fair products. The fact that HIF runs parallel to traditional patents allows firms certain flexibility in deciding which system offers the better returns for them. Unlike the other pull mechanisms, it offers a better long-term sustainability as it doesn't upset the existing balance of cost-effectiveness that the pharma industry is used to. Indeed, a major review of the current ideas to increase access to medicines has found HIF as the only mechanism to cover both accessibility and availability issues without any medium or long term disadvantages (Nathan 2007).

The Current Intellectual Property Rights Problematic

A patent is a basic exclusive licensing mechanism that allows the owner to exclusively market a product for a period of time. In pharmaceuticals this period is usually twenty years, although sub-patenting (e.g. patenting certain aspects of the production process or new variations of the existing product) can confer exclusive rights for much longer periods. This is actively pursued by the pharma sector that naturally attempts to maximize costs with the least intensive R&D effort, that results in perpetual ever-greening of exclusive rights and ring-fencing of innovations.

Since governments are the only legal entities that are able to confer patents, the supranational entity of the World Trade Organisation has been tasked with developing an agreement to regulate Intellectual Property Rights (IPR) issues at global level. The resulting Trade Related Aspects of Intellectual Property Rights treaty (TRIPS) has been the focus of heated discussions and hard negotiations amongst the different parties, most notably developed versus developing countries. The reason for the ensuing conflicts is that the current IPR regime works counterproductively for the majority of the world's population resulting in actually diminishing access to essential medicines instead of increasing it.

TRIPS is based on the assumption that strong enforcement of exclusive licensing, as undertaken in developed countries, is desirable at global level in order to enhance innovation. Although this assumption is based on sound argumentation that has proven correct in advanced economies, it is also highly problematic at global level since the majority of the world's states lack the necessary

infrastructure to compete adequately with developed countries in innovation. At the same time, most developing countries lack the necessary funds to purchase pharmaceutical products at existing pricing levels conferred by the current licensing agreements. This obvious paradox has been widely acknowledged and has become the main bone of contention between developed and developing countries in the negotiations over TRIPS.

Some developing countries, notably the main emerging economies, have taken the lead in negotiating a fairer treaty by insisting on the inclusion of corrective measures. For instance, India along with other developing countries including Brazil, China and Colombia have expressed their objections to the current thinking in TRIPS and have highlighted the need to preserve enough flexibility in regulating IPRs to protect public morality, public health and to promote the public interest (Srinivas, 2010). This amounts to a considerable re-think of IPR rules when applied at global level and in relation to medicines that are seen as essential.

The ensuing debates have resulted in a provision within TRIPS that allows a state in need to import essential drugs without paying the licensing fee provided there is a major public health need amounting to crisis (i.e. Compulsory Licensing). Despite the general understanding that such provision is necessary to facilitate urgently needed health care in many parts of the world, as is often the case, the devil is in the detail and the text of the final provision has been a severely watered down version of the original idea, that offers states little flexibility in terms of the conditions and manner in which the purchasing of license-free drugs can take place. For instance, the definition of public health emergency is vague and therefore disputable, while Compulsory Licensing is issued to countries that have no manufacturing capacities themselves and only for certain drugs from certain providers. Moreover the official approval process is open to severe delays due to allowances for raising grievances and objections by a high number of relevant stakeholders.

This situation has lead to protracted legal cases whereby some (developing) countries have issued compulsory licensing that other (developed) countries dispute as contravening the provisions of the Compulsory Licensing provisions of TRIPS. South Africa, Brazil and Thailand are prime examples of developing countries that have issues compulsory licensing for essential drugs only to be accused by developed countries that are acting in bad faith and even illegally. The complexity of identifying a genuine urgent public health need is considerable in such cases but the outcome of discussions eventually bolds down to simple imbalances in world trade and innovation amongst developed and developing countries.

As a result, the current state of the TRIPS agreement in relation to access to pharmaceuticals is highly unsatisfactory for the majority of the world. Notwithstanding the need to acknowledge and reward innovation, the current IPR system actually works as a barrier to increasing access to medicines rather than a facilitator. Reward has taken precedent over need and current global legislation is developing on this premise. The objections and efforts of many

developing countries to change this view and amend TRIPS accordingly has a moral merit that cannot be disregarded. Nevertheless, the state-of-art is a deadlock that after more than ten years of negotiations the world community has failed to resolve.

HIF attempts to function within this bitter process of global negotiations by actually by-passing the debate altogether. Its offer of an alternative IPR protection that does not conflict with the current system is a major advantage in that respect and perhaps its single most important feature. The freedom of pharmaceutical firms to opt for the "traditional" patent system (with all the pitfalls that it entails) or the alternative (dubbed "patent 2") system is the cornerstone of HIF. It is envisaged that the established pharma industry will opt for the existing system that knows well and works in their benefit, while the upcoming emerging economies pharma sector will opt for patent-2 as it can guarantee a fair return without complications due to marketing, distribution and litigation costs.

The Challenges for HIF

It is perhaps superfluous to mention that HIF is faced with considerable challenges if it is to become reality in the future. Any kind of mechanism that aims to increase access to medicines to ca two billion needy people is bound to face formidable challenges. We will briefly give an account of the main issues that HIF needs to tackle and offer possible solutions to them.

Measuring Impact

The whole idea of HIF is based on the assumption that measuring the impact of drugs in people's lives is possible. This could be disputed, not for lack of effort or evidence but perhaps for lack of consensus on what an acceptable impact assessment should be and what it should entail. There is considerable effort to measure the impact of medicines around the world as this is a cornerstone in the decision making process of private insurers and governments before accepting to cover costs of particular treatments. For this purpose, health assessment agencies have been established in most developed countries with the remit to offer evidence-based advice on the effectiveness of drugs and treatments.

There are different metrics used in relation to the general impact of treatments in people's lives, the most common ones being Quality Adjusted Life Years (QALYs) and Disability Adjusted Life Years (DALYs). QALYs account for the difference between good and bad health with good health given a value of 1 and bad health given a value between 0 and 1. The assumption is that a healthy year should count more than an unhealthy one. Naturally, the decision making process in QALYs includes evaluations on how much of a particular bad health state should count in relation to other bad health states. This is an issue of weighing that entails a number of subjective evaluations that eventually complicate the overall measurement. DALYs were developed by WHO with the same evaluation process as QALYs with the difference of being based on public

health data that attempt to account for disabilities in a more objective manner. Both QALYs and DALYs measurements are suffering from being based on many subjective evaluations, lack of intercultural comparisons on the meaning of bad health and inadequate quality of global health data.

Nevertheless, HIF needs to work within the existing framework of measurements with all its pitfalls. It cannot rely on clinical data alone as they are poor predictors of large-scale effects and they cannot account for co-morbidities that are the norm in developing countries. Hence, the common health assessment process undertaken in developed countries is inadequate for HIF. Moreover, QALYs and DALYs cannot account adequately for the great discrepancies that we find in different parts of the world in relation to identical health problems. For instance a particular disability could mean change of job conditions for a citizen of a developed country but total loss of family income for a developing country citizen. Hence, HIF will need to rely on better measurements of global health than the current one used for QALYs and DALYs.

Perhaps the single most important challenge in terms of measurement though, is the general lack of good health data in the developing world. Even the developed world is lacking good data in terms of use of drugs, side effects, long terms effects, co-toxicities, etc. The situation is even worse in the developing world that many states lack any data at all regarding the actual use of drugs and their effect in local people. HIF will need to start from scratch in this respect and devise methodologies that will produce adequate datasets to reach a fair decision on the impact of a particular medicine at global level. Here the burden of proof falls with the companies that register the drug with HIF. They are responsible to provide the proofs of effectiveness within the parameters given by HIF. To avoid fraud, a good auditing system should be in place along with good baseline data.

The main challenge therefore for HIF in the area of measurement is to construct a global impact assessment database that avoids the pitfalls of the current measurements. As Hollis and Pogge (2008) argue, this is perhaps a matter of adequate funding. Currently far too little money is spent in impact assessment and the need to improve the existing methodologies is evident. HIF will become a global player in health assessment by virtue of its remit. It will have to evaluate clinical studies, fund observational studies in the developing world, create databases for global drug use and audit existing data. This would be a win-win situation whereby better evidence could be created that will be used freely by all interested parties whether they are pharma industry, governments, public health experts or social scientists.

The Last Mile problem

The Last Mile problem is a key challenge for every idea to increase access to medicines for poor people. It refers to the issue of increasing access to existing drugs and ensuring proper compliance with instructions of use where there is lack of infrastructure to facilitate this. Even if existing drugs are provided at very low cost by manufacturers, this does not necessarily translate to low prices for

consumers. There is a number of added costs involved between manufacturer and consumer that include import duties, storage and transportation costs, pharmacy costs, etc. These costs can add up to turn a perfectly affordable drug at the point of production to prohibitively unaffordable at the point of purchase.

The second, even more complex, related problem is to ensure that the drug that arrives at the consumer's hands is actually used correctly. WHO estimates that 50 percent of all medicines are prescribed, dispensed, or sold incorrectly, and that about half of all patients do not take medicines as directed (WHO 2004b). The same report identifies the main problems as:

- Use of too many types of medicines per patient.
- Wrong or inadequate prescription of antimicrobials and antibiotics.
- Inappropriate use of injections that increase the transmission of blood-borne diseases.
- Failure to prescribe in accordance with clinical guidelines.
- Inappropriate self-medication.

A key cause of these problems is lack of appropriate health facilities and inadequately qualified health personnel. The poorer the country, the more acute the problem; and it becomes even more acute, the more rural the setting is, whereby physical inaccessibility exasperates the situation. Drug firms are usually providing their products at entry point (e.g. government health authorities or local private sector) without any means of ensuring accessibility or compliance.

One can hardly imagine a solution that will not necessitate large amounts of money and sufficient time lapse to develop a more effective health care infrastructure. But neither the money nor the time is in adequate supply. Despite correctly identifying the relevant problems, aid organisations are hampered by the vast scale of the effort to offer an acceptable solution that will result in increased accessibility to everyone in need.

HIF faces this challenge indirectly by having a payment structure that enhances incentives for speedy solutions. Since payment is made on the basis of robust proofs of impact, manufacturers and processors of medicines are incentivised to use their (sometimes considerable) local influence to increase access to specific products. This could take the form of promoting regulatory processes that allow for better price checks locally and/or partnering with local private sector to increase efficiency of distribution.

The issue of compliance is more complex but the solution is based on the same assumption to that of accessibility: the HIF payment system provides a powerful incentive for firms to improve compliance. This is already happening in the developed world whereby the pharma industry is regularly informing and training clinicians in the proper use of their products. This is not surprising since proper use translates into better impact and therefore, more income. The same reasoning though, should see the involvement of industry in promoting compliance by informing and training local personnel and keeping registers of

compliance along with those of impact as the previous section has described. So long as the impact assessment process is robust and widely accepted, there is little to worry about inappropriate strategies of compliance to maximize profits.

Political will

The world has long been aware of the problem of access to medicines and many ideas have been developed to address it, as described in the previous sections above. Governments and charities from the developed world have been active in trying to tackle the problem with varying degrees of success. Research programmes have been established to fund research on medicines for orphan diseases and other major diseases affecting the developing world. At the same time, we have witnessed the creation of global initiatives funded by governments and charities that attempt to tackle availability and accessibility at vast scales. Initiatives such as The Global Fund to Fight AIDS, Tuberculosis and Malaria or the European and Developing Countries Clinical Trials Partnership (EDCTP) are multibillion Euros organisations that work exclusively to increase access to medicines. Private foundations are also created with focus on drug availability (e.g. the Clinton Foundation). All and all, one could say that there is political will to do something about the dire state of health care in the world.

What is not clear however, is whether this will can translate into long-term commitment that is a crucial aspect of any relevant initiative. Both the Global Fund and the EDCTP are based on individual state contributions that are negotiated annually and are not even always forthcoming as promised. The danger that an important contributor would withdraw support with little warning is constantly present and a considerable threat to all of them. It is hard to attempt a long-lasting solution to such complex issues without long-lasting commitments. This is something that HIF needs to take into consideration in its design, from the administrative part to its guarantee to firms of long-term returns.

At present HIF is designed to receive government funding according to each state's Gross National Income (GNI). This is fair as it entails states contributing proportionally to their wealth and at equal levels of contribution. The current funding projection is at 0.01% of GNI that is not an unreasonable contribution in relation to the aid expenditure of most states and the scope of the organization. Most developed states have undertaken to contribute up to .7% of their annual Gross Domestic Product (GDP) to development aid. Few states have achieved this number but most are above the 0.3% threshold. A .01% of GNI (akin to GDP) is therefore achievable. That is, once the political will is there.

So far, the signals for political support for HIF are mixed. Occasional complimentary comments have not yet been translated into hard cash. A major success is the inclusion of HIF in the development policy manifesto of the German Social-Democratic party that has undertaken to support it, if it becomes government. With a major European government backing HIF, it would have a good chance to become reality at least for a testing period.

The way ahead

We have described the main aspects of HIF, its location within similar initiatives, its relationship to the current IPR regime and the main challenges it faces in order to become reality. Where do we go from here? An idea might be great but it is not very useful as long as it remains just an idea. HIF is ready to step into the implementation phase once few conditions have been met. Perhaps the most important one is financial backing but it is by no means the only one. Every single challenge described above needs to be dealt with successfully. This is a toll order but there can be no short cut for an initiative that aims to change the health conditions for millions of people. Nevertheless, there are certain steps that are perhaps necessary to provide a chance of implementation in the near future. These are summarized as:

Achieving critical mass

The first step that is needed to realize HIF is achieving a critical mass of support. This does not mean only political support, although this is naturally critical for funding purposes, but also opinion leaders support. This refers to experts in the area of development and public health and, crucially, also health officials in developing countries. Acceptance by the expert community in developed countries would allow for visibility where it matters most: government agencies that decide on development aid budget spending. As with all other aspects of government spending, decision-making follows processes involving expert evaluations, condition-dependent recommendations and final approval. Being accepted by the expert community as a viable alternative, is a necessary step in reaching the level of positive recommendation in the process of decision making.

However, one ought not be making plans attempting to change peoples' lives without consulting those people themselves. Development aid has long suffered from a "messianic complex" whereby solutions were offered to unwilling recipients under the assumption that an outsider expert is better equipped to manage aid than an insider non-expert. Often though, this is simply not true and development aid nowadays is far more inclusive and accepting of local realities than ever before. In the same manner of thinking, HIF should target involvement of local experts and officials with the same zeal that it targets possible funders. Only when discussed with the target population (and amended accordingly) recipients will acquire a notion of ownership and control of the process that will make it eventually successful. As the functioning of HIF depends on the cooperation of local authorities from the accumulation of health statistics, to amendments in pharma law or re-organisation of distribution infrastructure, local authorities ought to be involved already in the pre-implementation design of HIF. Moreover, it is unlikely that wealthy countries will agree to a long-term commitment without strong support by those that they ultimately aim to help.

Piloting HIF

A full implementation of HIF would require a minimum of ca 6 Billion Dollars funding and 10-12 years of continuality, according to the initiators of the idea (Hollis & Pogge, 2008). This requirement is based on a rough calculation on the availability of registered drugs and the time it takes to guarantee a satisfactory return for firms through the system. $6Billion of funds represents a very small amount of the overall drug expenditure and a not too big percentage of the overall development aid expenditure in the world, but it is still a considerable amount to be invested in an untried idea.

Since it is reasonable to expect that potential funders would like to see evidence, even preliminary, of the efficacy of the system, HIF should be accordingly piloted to collect such evidence. This is a complex undertaking since the system is geared towards widespread implementation, preferably at global scale. Piloting should be local enough to guarantee full impact assessment and cheap enough to allow for adequate funds to be collected on time. A pilot study would be unlikely funded by a government but it might well be funded by a charitable organization or individual.

A key prerequisite for piloting would be a welcoming local government of a developing country to allow for full use of its public health databases, systems of distribution and health officials to facilitate data collection. Such willing government has not been found so far, to our knowledge, but it is conceivable that it will eventually be forthcoming. The reason is that a pilot study of HIF presents a win-win situation for both the organization and the government. It should prove the efficacy of HIF and even result in improvements in the concept, but at the same time it will provide greater access to (at least some) medicines for the population and it will create better public health databases for general use beyond HIF. In any case, a pilot study is a key to the development of HIF and should be hotly pursued.

Promote regional alternatives

HIF is an initiative aiming at global outreach and it is designed to function as an international institution funded mainly by governments. Its suggested administrative structure (including the key technical and impact assessment departments) is geared towards global assessments and the creation of global databases. But this need not be the only manner in which HIF can be applied to increase access to medicines. One could well envisage a special focus in terms of both technical and geographical scope that would nevertheless achieve the main aims of HIF.

One such idea has been developed by colleagues from the Indian Research and Information Systems for Developing Countries (RIS) and Chinese Academy for Science and Technology for Development (CASTED). Their idea is to develop a regional variation of HIF with exclusive focus on Traditional Medicines (TM) that

will involve only India and China (RIS and CASTED, 2010). They have dubbed their joint initiative the China- India Traditional Medicine Health Impact Initiative (CITHII). This is envisaged initially as a bilateral fund, confined to the firms and research institutes from the two countries alone, but later on may be opened to other countries and regions as well. CITHII will combine the objectives of the HIF with relevance to TM in both countries and hence will be a win-win approach for the HIF. CITHII draws on HIF's core objectives and links that with the public health needs in both countries. In that sense CITHII is a regional variation on the idea of the HIF.

The objectives of CITHII as developed in the report of RIS and CASTED are:

- CITHII should be developed to encourage the innovation of TM in both countries so as to address the health requirements of poor populations, and should also explore how best TM may also serve global objectives by evolving criteria for the selection of drugs at cost effective terms. Planners in both countries are aware of the importance of TM and both countries have plans to use TM in a big way. So CITHII will be compatible with the thinking of policy makers, and the policy frameworks in both countries can be conducive to CITHII
- CITHII may also support developing uniform standards for drug trials and impact assessment. This may further be extended to evolve a common methodology for clinical trials. The work at the ISO established (TC429) Technical Commission for Standardisation of TCM at Shanghai, may be utilised for joint gains. There is no agency so far in either of the economies for impact assessment. As Indian systems of medicine and TCM are widely used in other countries in Asia such a plan on clinical trials' standardisation would be relevant for them also. Both India and China can take the lead in this and use this to facilitate South-South and regional co-operation in TM.
- Scientific validation of single/simple formulation for developing herbal drugs, facilitating product development, technology transfer, commercialization and benefit sharing can be some of the objectives of CITHII. To begin with, CITHII can identify priority areas/issues and focus on them.
- Conservation and cultivation of selected medicinal plants for developing balanced ecological approaches. This may need the introduction of R&D activities to deal with the implications of climate change on medicinal/food plants. Both India and China are parties to the CBD and have strong research programs and action plans on climate change research. There is enormous scope for bilateral co-operation and joint research in this. It is possible to develop integrated approaches to medicinal plant conservation, their utilization in TM, research on medicinal plants and sustainable use of medicinal plants. CITHII will fit well within such approaches and will be compatible with plans on medicinal plants and TM.

The CITHII regional development of HIF appears therefore desirable and viable and in full agreement with government policies for the development of TM in

both China and India. As such, it represents and new and powerful alternative to a full blown HIF that would require considerable negotiations and resources involving too many stakeholders. Thus, the efficacy of the idea can also be tested in a way that would also satisfy the requirements of a pilot testing as described above.

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