

STUDENT VOICES 4

Assessing Proposals for Access to Medicines Reform



Student Voices 4: Assessing Proposals for Access to Medicines Reform

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Rapid HIV testing in Marondera, Zimbabwe.

About the McMaster Health Forum

For concerned citizens and influential thinkers and doers, the McMaster Health Forum strives to be a leading hub for improving health outcomes through collective problem solving. Operating at the regional/provincial level and at national levels, the Forum harnesses information, convenes stakeholders, and prepares action-oriented leaders to meet pressing health issues creatively. The Forum acts as an agent of change by empowering stakeholders to set agendas, take well-considered actions, and communicate the rationale for actions effectively.





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Forward

The barriers preventing access to medicines and other health technologies for diseases that affect the global poor are complex. The World Health Organization (WHO) has discussed this challenge for almost 10 years in an attempt to balance intellectual property rights, incentives for innovation, and improvement to public health through the development, availability and access of affordable health products.

Over 130 proposals have been put forward during this period suggesting new mechanisms or policy reforms. Analyzing these proposals is challenging because there are different interests at stake which affect political feasibility no matter their theoretical merit. The fact that few of them have been implemented, piloted, or empirically evaluated add to these challenges.

It is therefore very encouraging that students at McMaster University have boldly taken on this task as part of their studies. These students, in many ways, have acted as a “shadow expert group” to the formal Consultative Expert Working Group (CEWG) that I had the honour of chairing and whose members were appointed by the WHO Director-General. This student report presents evaluations of 15 grouped proposals that were also examined by the CEWG. The evaluations have used the same set of criteria agreed upon by the CEWG at the outset of our work and mirror in this way the assessments we carried out. I am impressed by the level of understanding and the rigorous analyses provided by these students in their assessments of the proposals, and I believe they nicely complement and bring forward new substantive contributions to the assessments we published in the final CEWG report. I hope it has been motivating for the students to work on real-world problems in a real-time manner.



Professor John-Arne Røttingen and WHO Director-General Margaret Chan presenting the recommendations of the Consultative Expert Working Group to the World Health Assembly on May 22, 2012

The evaluations and this student report have partly been possible because the CEWG made sure to work in an open and transparent manner, including inviting submissions and sharing preliminary work on our website. When difficult policy problems have not been solved for a long time, it is often because they are both complex and there is a lack of political will for change. It is therefore important to include all stakeholders in such work and to benefit from all perspectives when developing solutions to these challenges. Students represent an important resource and constituency, and they are probably not utilized or involved as much as they ought to be.

In this way, this excellent student report also speaks to a broader issue of global importance. It demonstrates the value that young people bring to the table and that we should involve them more when working on difficult policy areas like access to medicines. Young minds represent hard working abilities, innovative ideas and the willingness to pose critical questions, and confront the status quo. We need more of their creative energy and appetite for change in global health. Maybe future processes like the one undertaken by the CEWG will also benefit from having “shadow student groups” which independently work on the same issues as the formally appointed group. This would foster richer debate and deeper discussions.

I would like to commend the students and their professor, Steven Hoffman, for this excellent report that will no doubt contribute to further discussions now that the CEWG report was considered by the World Health Assembly in May 2012 and a follow-up process has been planned. One thing is for sure, which is clear from reading the students’ evaluations: the status quo is not an option.

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August 2012

Introduction

The twin challenges of fostering innovation and access to health products has long been one of the greatest barriers preventing better global health, especially for the world's poorest people. Patents incentivize private sector research and development (R&D) on products for which there are sufficiently large markets of people who can afford high prices, and public government funding is largely limited in both scale and scope to diseases and conditions that affect their citizens.

As time passes, the global health community is increasingly experiencing fragmentation with its ever-expanding cast of players, divergent interests and conflicting agendas. Calls for access to medicines reform have recently grown louder to change the way that R&D for medicines and other health technologies are coordinated, financed and prioritized. These calls recognize that medical research is not being organized as effectively as possible, and that innovative solutions to current access barriers are needed to achieve the health-related Millennium Development Goals, global health security, and other priorities of the international community.

New ideas are floated every day for better ways to achieve innovation and access to medicines. Some proposals call for total transformation while others suggest small changes. Some rely on existing institutions while others propose new organizations. Some seek to solve all the problems preventing innovation and access all at once while still others focus narrowly on one or two particular challenges.

Given the importance of medicines and health technologies to the health, well-being and human rights of people around the world, all proposals are worthy of consideration, but none deserve implementation without such consideration. Indeed, most would agree that future reforms, like all important decisions, must be informed by the best available research evidence and most creative insights.

This edited volume offers evidence-based assessments of fifteen prominent proposals for access to medicines reform that were considered by the World Health Organization's Consultative Expert Working Group on Research & Development: Financing and Coordination (CEWG). These include proposals for:

1. Patent Pools
2. Equitable Access Licences
3. Open Source and Pre-Competitive R&D
4. Orphan Drug Act
5. Priority Review Voucher
6. Regulatory Harmonization Proposals

7. Product Development Partnerships
8. Tax Breaks
9. Green Intellectual Property
10. Prizes
11. Advanced Market Commitments
12. Health Impact Fund
13. Biomedical R&D Treaty
14. Removal of Data Exclusivity
15. Transferable Intellectual Property Rights

Each chapter relies on an extensive review of the available research evidence and a broad range of insights to: (a) summarize the key elements of each proposal for access to medicines reform; (b) identify the needs it seeks to address; (c) examine the extent to which it would meet the twin needs of fostering innovation of new technologies while facilitating access to existing ones; (d) analyze the proposal's political attractiveness; (e) raise implementation considerations such as costs, risks, possible harms, feasibility and equity; and (f) offer recommendations on whether the proposal should be further explored for possible implementation. The evaluation criteria was adopted directly from the one used by the CEWG.

The authors of this report are all students at McMaster University who prepared these essays for a fourth-year undergraduate course on Global Health Governance, Law and Politics (HTH SCI 4LD3) that was offered from September to December 2011 by the Bachelor of Health Sciences (Honours) Program in collaboration with the McMaster Health Forum. In publishing this report, it is our belief that today's students have an important role to play in global health decision-making for both their innovative ideas and future leadership of the global health community. Through this publication, it is hoped that these students can help shape the future of access to medicines reform while preparing themselves to confront tomorrow's greatest challenges.

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August 2012

Chapter 1

Patent Pools, Equitable Access Licences, and Open Source and Pre-Competitive R&D

Piyumi Galappatti, Sofija Rans and Adrian Tsang

Introduction

Research and development conducted in the biotechnology sector today frequently involves partnerships between the public and private sectors, with universities and other public research facilities acting as the main source for core technologies and compounds that are later developed into pharmaceuticals. Patents are used in many sectors today as a way of recouping high R&D costs, and to protect innovations from the increased threat of duplication posed by advanced reverse engineering methods. Additionally, domestic-level innovation policies such as the American Baye-Dohle Act of 1980 and international regulations such as the World Trade Organization's Trade-Related Aspects of Intellectual Property (TRIPS) framework, have made patenting a widespread practice.¹

However, the market exclusivity granted by patents and high costs of pharmaceutical R&D result in prohibitively expensive drugs, making them inaccessible to the world's poor.² The current patent system for drugs also provides little incentive for R&D investments toward diseases that primarily affect low- and middle-income countries (LMICs), due to the lack of profitability. These conditions prevent individuals from accessing the treatments they need, and severely constrain progress towards achieving global health goals. In order to effectively address this current access gap, new strategies of managing intellectual property (IP) are needed to increase the affordability of pharmaceutical products and incentivize research into neglected tropical diseases.

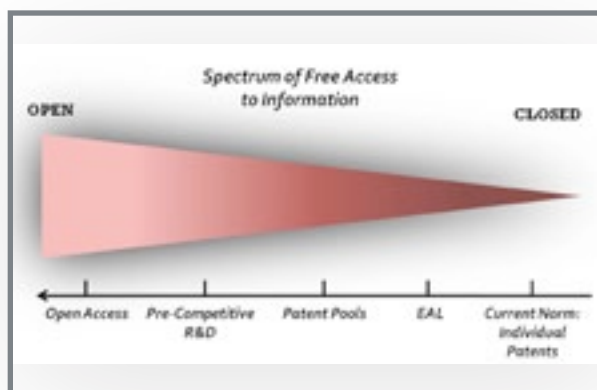
This paper evaluates three proposals – patent pools, equitable access licences, and open source and pre-competitive R&D – based on an adaptation of evaluation criteria outlined by the World Health Organization's Consultative Expert Working Group on Research & Development. Each proposal's potential health impact was assessed based on its ability to incentivize R&D and increase access and affordability of medicines. Without funding mechanisms embedded in these three proposals,

Abstract

Patent pools, equitable access licences, and open source and pre-competitive research and development platforms are three proposals that attempt to address the issues of affordability and availability of medicines that occur due to the high costs of pharmaceutical R&D, and the existence of patent monopolies. Patent pools and open source and pre-competitive R&D offer strategies to streamline the drug development process, reducing costs for producers, while equitable access licences attempt to decrease drug prices by increasing generic competition. While all three proposals present cost-effective solutions, there are considerable challenges to their implementation, namely those related to enforceability, accountability of actors, free-riding behaviour and high start-up costs. Additionally, they fail to provide a workable solution to the lack of R&D expenditures towards neglected tropical diseases (NTDs) and low rates of commercialization among drugs targeting NTDs, which constitutes an important part of the 'access' gap. In order to achieve universal access to medicines, solutions are needed not only to make medicines more affordable, but also to address gaps in delivery and provide a mechanism for sustained innovation in the biotechnology sector.

cost-effectiveness specifically refers to the relative cost required to operate these mechanisms to best achieve their policy goals. Operational efficiency and feasibility address whether a proposal can operate within current legal, regulatory or administrative systems, and whether it is likely to be widely accepted by stakeholders. These criteria also consider whether the proposal will be sustainable and adaptable in light of actual experience, and the transparency and accountability of its governance structure.

Figure 1: Spectrum of Free Access to Information



This figure illustrates the extent to which each of the proposals conform to the existing IP regime by presenting a spectrum between the current norm of individual patents and open access. EAL represents “equitable access licences.”

Patent Pools

Having been successfully implemented in other industries, patent pools were introduced in the biotechnology sector to counter the hampering effect excessive patenting has had on innovation. Overlapping patent rights force innovators to obtain multiple licences from multiple patent holders — a situation that has been commonly referred to as the “tragedy of the anti-commons”, which occurs all too often and stifles innovation.³ Patent pools allow multiple patent holders to group their IP and license out their patents to one another or to a third party. Those wishing to make use of a patented product may obtain licences from this “one-stop shop” in exchange for a royalty payment set by the governing



Nine-month-old Emabet is about to receive her measles vaccination, in Ethiopia's Merawi province. Pete Lewis, Department for International Development, 2011.

companies.³ If managed effectively, a patent pool would make the drug development process more efficient by centralizing licensing procedures.⁴

Potential Health Impact

Patent pools are able to achieve price reductions and increase the availability of medicines because they allow producers to manufacture and distribute patented medicines before the patent term ends, by gaining multiple licences from the same pool.⁵ These licences issued for the purpose of commercialization in LMICs result in increased competition between generic manufacturers, which leads to increased distribution and ultimately drives down costs for patients. In the case of UNITAID's patent pool,



licences can also be granted for the purpose of collaboration in developing drugs for low-income populations, such as antiretrovirals for children.⁶ Furthermore, patent pools can improve the safety and quality of medicines in LMICs through regulated licensing.⁷

Cost-Effectiveness

The patent pool model requires minimal start-up and operating costs because it works within the patent laws, which mitigate R&D investment risks for shareholders.⁴ For IP users, the streamlined licensing process in patent pools is designed to increase efficiency in further R&D and generic development. For patent holders, it creates a sufficiently large

market to provide the potential for greater royalty income.⁵ Additionally, patent pools are a more attractive alternative to compulsory licensing which is initiated by individual countries and results in firms having access to a smaller market.³

Operational Efficiency and Feasibility

Patent pools distribute the risks associated with investing in drug development. Depending on the revenue-sharing model of a patent pool, patent holders may receive a certain share of the royalties regardless of the ability to link the development of a particular medicine to their patent.⁸ While this may encourage holders of less important patents to contribute to the pool, firms with potentially highly profitable drug or technology patents may be less eager to share royalties with other members. The successful operation of a patent pool in the pharmaceutical sector is contingent upon the establishment of a revenue-sharing model that encourages patent holders to pool together important and potentially lucrative patented technologies.

Due to their operation within the existing system of patent protection, patent pools present a conservative IP management strategy and can be operationalized quickly, based on extensive historical precedents and within the existing legal structure.³

In order for a patent pool to function efficiently, patent holders would have to voluntarily offer IP protected by patents into a pool.⁴ The telecommunications industry benefited from voluntary patent contributors because widespread use of the developed technology enhanced a firm's key product or complemented its business model. Patent pools have been used successfully in the accelerated development of electronics and telecommunications technologies (e.g., Bluetooth, radio, MPEG 2, DVD).³ In contrast, biotechnology companies are often unwilling to expose weak patents or ongoing research plans for which breakthroughs are expected. Biomedical discoveries (such as patented receptor complexes or genes) are also less likely to have



substitutes.⁶ The original patent becomes more economically significant when competitors are unable to invent alternatives and a patent holder is thus less likely to join a patent pool.³

Due to the large costs involved and high risk nature of pharmaceutical research, the biotechnology industry relies heavily on patent protection to recoup costs and secure large profits to please investors. Patent holders are unlikely to voluntarily contribute their patented products if it reduces their profit margin, resulting in difficulties in patent pool creation. Finding common ground for these actors poses a considerable challenge to the feasibility of patent pools. Convincing stakeholders, especially private companies, to contribute voluntarily to patent pools is further challenged by the fact that few biotechnology firms are vertically integrated. Vertically integrated firms control all stages in the production of a good. Since vertically integrated firms make a considerable portion of their profits downstream, they would be likely to join a patent pool to reduce their costs downstream. In other industries, patent pools are attractive to vertically integrated firms, which benefit from the production and distribution of a product as well as royalty revenues, especially if their patents are the standard of the industry.⁸ Aside from large pharmaceutical companies, the majority of stakeholders in the biotechnology industry are R&D oriented firms that

are rarely vertically integrated and earn a considerable amount of their revenues through licensing payments.⁸ If these firms own essential patents of high economic value, they may choose to hold out their patents in hopes of negotiating higher royalties that are not diluted by the rest of the pool.⁸

The patent system and anti-monopoly regulations are tightly intertwined. Patent pools have been portrayed as a tool for cartelization and a mechanism for industry control because of the entry barriers they create.⁹ Managed improperly, patent pools could cause anti-competitive effects if the patent pools cover all of the competitive alternatives to a certain medicine for a particular neglected disease, resulting in the potential for collusion and price fixing.¹⁰ A precedent of patent pools violating antitrust laws has been set. Patent pools were dismantled in 1945 (in glass production) and again in 1975 (in the aviation industry) because production in their respective industries was controlled by a small number of patent holders.³ Patent pools have also resulted from companies who settle after fearing the validity of their patent will not be upheld in court. A naturally occurring substance (e.g., gene sequence, biological molecule), for example, cannot be patented. This legal pathway allows companies to charge royalties on patents which should already be part of the public domain.³ The U.S. Department of Justice and the Federal Trade Commission, the European Commission, and Japanese Fair Trade Commission have all issued guidelines outlining procedures to curtail the potential anti-competitive effects of patent pools, while indicating a potential for pro-competitive benefits.³ Fortunately, due to these guidelines, the administration of patent pools in an accountable and transparent manner is more clear.

Equitable Access Licences

Equitable access licences focus on reforming technology transfer agreements made between universities and private partners to ensure that the end-products of publicly funded research are used in a manner that advances the public good.¹¹ While many conceptualizations of an equitable licence

are possible, much of the existing literature focuses on the scheme developed by the student-led group Universities Allied for Essential Medicines (UAEM), which facilitates the entry of generic producers to drive down prices of drugs.¹² Under this model, equitable access licences ensure that when a university licenses a health-related technology to a private firm, it retains the right to grant additional sub-licences for the final products and any derivatives of the initial product to a third party generic manufacturer that would market them in LMICs.¹²

Potential Health Impact

While past observations of generic entry driving down prices of products demonstrate the potential of equitable licences to significantly increase the affordability of drugs, the licence fails to address gaps in R&D for neglected diseases and their delivery, which are important components of accessibility to medicines. Additionally, the impact of equitable access licences is limited to the long-term for two reasons. First, they can only have an impact on future drugs that are not already licensed. Second, they target early-stage research conducted in universities and, as a result, effects only appear many years later, downstream in drug development. In the United States, it takes on average 16 years for a drug to be developed, undergo clinical trials, gain FDA approval and be brought to market.¹³ Furthermore, additional time may be required for generic companies to acquire the necessary licences to produce the drug, further delaying the effect of equitable access licences on the price of drugs and on the health of individuals in LMICs.

Cost-Effectiveness

Equitable access licences are cost-effective in the sense that their self-implementing mechanism minimizes the transaction costs for generic manufacturers wishing to supply the end products of patented research in LMICs. Typically, a producer seeking to supply a patented medicine would have to negotiate permission with the patent holder, which would involve considerable time and legal fees.¹⁴

Additionally, it could be argued that equitable access licences make public research investments more cost-effective by making the end-products of those investments available to a larger number of people.

Operational Efficiency and Feasibility

Equitable access licences present a legally enforceable mechanism to ensure that generic producers are able to bring patented medicines to LMIC markets. According to the developers of the proposal for equitable access licences, a third party is required only to notify the university and patent-holding company of the need to supply a product licensed under the equitable licensing scheme in order to receive a sub-licence, which would be granted automatically.¹⁴ While this situation seems ideal, the realities of university-industry technology transfers pose challenges to the successful operation of this scheme.

A significant challenge to this proposal will be in getting industry partners to agree to the conditions of the licence. Specifically, the “freedom to operate” clause, which would allow a third party to supply the patented product in any LMIC country may be problematic. While private partners would not be too concerned with the supply of generics in low-income countries, middle-income countries such as China, India and Brazil provide lucrative markets, and would be hesitant to allow generic manufacturers to have a market share.¹² However, many generic producers with sufficient manufacturing capacity are based in middle-income countries, and excluding them would reduce the potential for equitable access licences to achieve their intended effects.¹² Industry partners may also be hesitant to grant back licences for improvements to the initial technology, especially if those improvements were costly to develop. Convincing private partners to agree to equitable licensing conditions may require amendments to the licence as well as costly negotiations. Collective adoption of the equitable access licence by universities, however, could significantly increase their bargaining power in this respect.





In spite of these difficulties, for universities at least, the adoption of equitable access licences is considered to be financially viable. First of all, revenues generated through technology transfers typically only represent a small fraction of a university's total revenue. Secondly, although patenting is becoming increasingly popular in universities, it more often than not results in monetary losses.¹⁵ Thus, the adoption of equitable access licences is expected to have a limited impact on a university's total revenues.

Open Source and Pre-Competitive R&D Platforms

Open source and pre-competitive R&D platforms aim to foster collaboration and encourage the sharing of ideas and information between multiple sectors by providing access to resources that may not otherwise be available publicly.¹⁶ Open source approaches build on the idea of online communities of researchers and scientists from industry and academia, where contributors can collectively discover new therapies for diseases. Anyone can freely use the resources and input ideas.¹⁷ Current examples of open source approaches in biotechnology include Synaptic Leap and the Tropical Disease Initiative, India's Open Source Drug Discovery projects, and Cambia's Patent Lens and Initiative for Open Innovation.¹⁸⁻²¹

Pre-competitive R&D is not designed to develop end-stage products,²² but instead, focuses on "enabling" technologies, highlighting promising treatments and providing research prototypes. Pre-competitive R&D is often achieved through public-private partnerships and the sharing of portfolios between multiple firms.²² Since their findings are not owned by one individual company, they are described as pre-competitive.²³ Current examples of pre-competitive R&D include the European Commission's Innovative Medicines Initiative and the Program for Appropriate Technology in Health.²⁴⁻²⁶

Potential Health Impact

Open source and pre-competitive R&D platforms have the potential for increasing the availability of medicines in LMICs, as they decrease the cost of medicines and allow for timely access to new drugs by reducing the time involved in researching new drug development.²⁷ This reduction in cost and time is accomplished through the sharing of data, expertise and resources to increase collaboration, transparency and cumulative public knowledge.²⁷ However, the extent of this impact is dependent on the focus of the R&D. In order to have a meaningful impact on access to medicines in LMICs, open source and pre-competitive R&D must focus on LMIC needs, not necessarily commercial incentives. Investing in open source and pre-competitive R&D through life science convergence platforms could ensure that the capacity building within LMICs required to facilitate targeted R&D occurs.²⁸ Local researchers and developers are most aware of both the needs and financial restrictions within their communities and can help ensure R&D efforts are directed at immediate needs.^{27,28}

Cost-Effectiveness

Open source and pre-competitive R&D approaches are cost-effective due to their ability to de-link R&D costs and the price of products. By focusing on collaborative efforts, they enable rapid advances in a variety of activities that are, to a large extent, conducted independently.^{27,30} By focusing on the early prediction of success or failure in drug development, production costs are lowered.²² Furthermore, open source and pre-competitive R&D address the problems of high R&D costs in the biotechnology sector, by channelling funds into the most promising projects. In doing so, they reduce duplicate research and provide investors the most 'bang for their buck'.

Operational Efficiency and Feasibility

The operational efficiency and feasibility of open source and pre-competitive R&D proposals is

challenged by a substantial amount of up-front costs, and dependence on both public and private investment to succeed. Unlike in the software industry, which experienced great success with open source discovery, open source approaches within health R&D are reliant on high cost technologies such as lab equipment, as well as being privy to knowledge of safety and regulatory issues.³¹ Open source software development requires few resources other than the contributor's time, compared to the \$802 million investment required to develop the average pharmaceutical product.³²

Currently, neither approach provides sufficient financial incentives for either universities or pharmaceutical companies to invest in R&D applicable to LMICs. This is especially true for the case of open source approaches, where contributors forego their IP rights once their research outputs are placed in the public domain. Open source approaches do not complement the current patent law system; thus the technical feasibility of this proposal is challenged.³³

Furthermore, since open source drug discovery occurs within the public domain and participants face no legal obligation to share their advances, there is the risk of participants choosing to patent discoveries that made use of the knowledge available in open source databases, rather than make them available to others.³³ The lack of incentive to forego IP rights, in combination with the actual cost of patents and tendency of companies to protect their IP in order to secure a higher return on investment, presents a very real obstacle to the implementation of open source and pre-competitive R&D approaches, especially those enabling full access.

Conclusion

While all three proposals address the access gap in LMICs, the potential health impact of equitable access licences is limited as its approach only impacts the affordability of future drugs and does not propose a mechanism to increase R&D into neglected diseases. Open source and pre-competitive R&D platforms show the greatest potential for achieving

health impact in LMICs, due to their ability to de-link the cost of final products from R&D costs, and their potential for capacity building within LMICs, if used in concert with life science convergence platforms. Unfortunately, the general reluctance of stakeholders to voluntarily contribute due to heavy reliance on patents to ensure IP rights and the high costs of capital investment, make open source and pre-competitive R&D an unfeasible option in the current landscape. The equitable access licensing scheme is more technically feasible because it does not require a systemic change, but ultimately, the collective reform of university technology transfer policies required will be difficult to achieve. Barriers to patent pools lie in defining the policies under which a patent pool will operate. The governance structure of patent pools will be especially important for achieving transparency and accountability, averting anti-trust practices and ensuring a sufficient amount of important patents can be contributed voluntarily for neglected diseases.³⁴

Open source and pre-competitive R&D also face challenges in implementation due to the difficulty in shifting toward an openness ideology. Patent pools face a similar struggle with voluntary contribution, but its existence within current patent laws is appealing as a more conservative option. Perhaps it is multi-stakeholder initiatives between industry, policymakers, funding agencies and researchers that will ultimately merge this dichotomy. The Bermuda Principles established during the development of the Human Genome Project achieved this synchrony between funders, resource producers and resource users.³⁵ True to open source initiatives, these principles established the immediate release of pre-publication data as a norm in genome research. More importantly, an administrative system was established in which researchers would only receive funding from government-sponsored funding agencies based on their adherence to those principles.³⁴ Furthermore, these principles were publicly endorsed by then President Bill Clinton and British Prime Minister Tony Blair.³⁶ If criteria similar to the Bermuda



Principles were established within biotechnology R&D for LMICs, it would facilitate the integration of both open source and pre-competitive platforms, as well as equitable access licensing, as firms would need to abide by these principles to receive funding.

There remains an ongoing debate as to the most effective way to facilitate advancement in R&D. Proponents for the use of IP laws insist that patent protection and its subsequent commercial benefits are required to justify such investments. Supporters of open source hold the belief that collaboration will ultimately result in the greatest efficiency in the research process, often citing the important successes in the Human Genome Project and examples from software and telecommunications industries. It is important to understand that health is an entirely different sector on which it is difficult to assign value, and additional responsibilities are placed on those with explicit knowledge. These significant differences may be to blame in creating the biotechnology industry’s detrimental reliance on preserving IP as it currently stands. Finding the ideal common ground among achieving the greatest health impact, operational efficiency, feasibility and cost considerations will prove to be difficult and will most likely involve a paradigm shift that challenges current norms.

Actionable Key Messages

- ⇒ The widespread use of patents in the biotechnology sector stifles innovation and results in artificially high drug prices, making them inaccessible to the world’s poor.
- ⇒ Patent pools provide innovators with a ‘one-stop-shop’ to reduce the costs of obtaining multiple licences separately, but in order to operate successfully, requires a revenue-sharing model that encourages patent holders to contribute economically important technologies. Careful monitoring is also required to ensure that the pools do not violate competition laws.
- ⇒ Equitable access licences target early-stage drug research and enable generic competition through a self-implementing mechanism, minimizing transaction costs and resulting in decreased drug prices, but their successful implementation may be threatened by difficulties in obtaining private sector approval.
- ⇒ Open source and pre-competitive R&D platforms make use of public forums to screen and channel funds into the most promising technologies, but require substantial up-front investments from both the public and private sectors, and run the risk of being abused by third parties who make use of the open information for commercial gains.
- ⇒ Increasing access to medicines will involve a paradigm shift in industry norms and the consideration of multi-level stakeholder agreements in order to achieve unified policy goals between funding agencies, researchers and commercial interests.

Table 1. Comparative Evaluation of the Proposals

Proposals	Technical Feasibility	Operational Feasibility	Accountability Governance and Transparency	Cost-Effectiveness	Potential Health Impact
Patent Pools	High	Moderate to low	Moderate to low	High	Moderate
Equitable Access Licensing	Low	Low	Moderate to high	Low to moderate	Low
Open Source and Pre-Competitive R&D	Low	Low	High	Low	High

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Chapter 2

Orphan Drug Act, Priority Review Voucher, and Regulatory Harmonization Proposals

Grace Bravo, Jessica Kapralik and Monis Khan

Introduction

Access to medicine, as advocated by the WHO through establishment of the Millennium Development Goals, has become an essential focus of the global health agenda.¹ Within access to medicine, a primary concern is the health impact of neglected and tropical diseases (NTDs), which affect approximately 1 billion people worldwide.² The U.S. Food and Drug Administration (FDA) has defined NTDs as tropical or infectious diseases “for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations” (e.g., tuberculosis, malaria, cholera).³ Between 1975 and 1999 only 16 chemical entities were marketed for NTDs, indicating a need for innovation and increased research and development (R&D) into NTD treatments.⁴ Three proposals submitted to the WHO’s Consultative Expert Working Group (CEWG) prescribe an Orphan Drug Act (ODA), Priority Review Voucher (PRV), and Regulatory Harmonization programs for addressing this need to stimulate and coordinate greater commitment to treating NTDs. The following report evaluates these three proposals based on the following criteria: the extent to which it can strengthen pharmaceutical research and development (i.e., through innovation or coordination), its political attractiveness, and its implementation considerations (i.e., operational and financial feasibility). Additionally, recommendations are made taking into account the necessary balance between competition and coordination in the global pharmaceutical market structure.

Orphan Drug Act

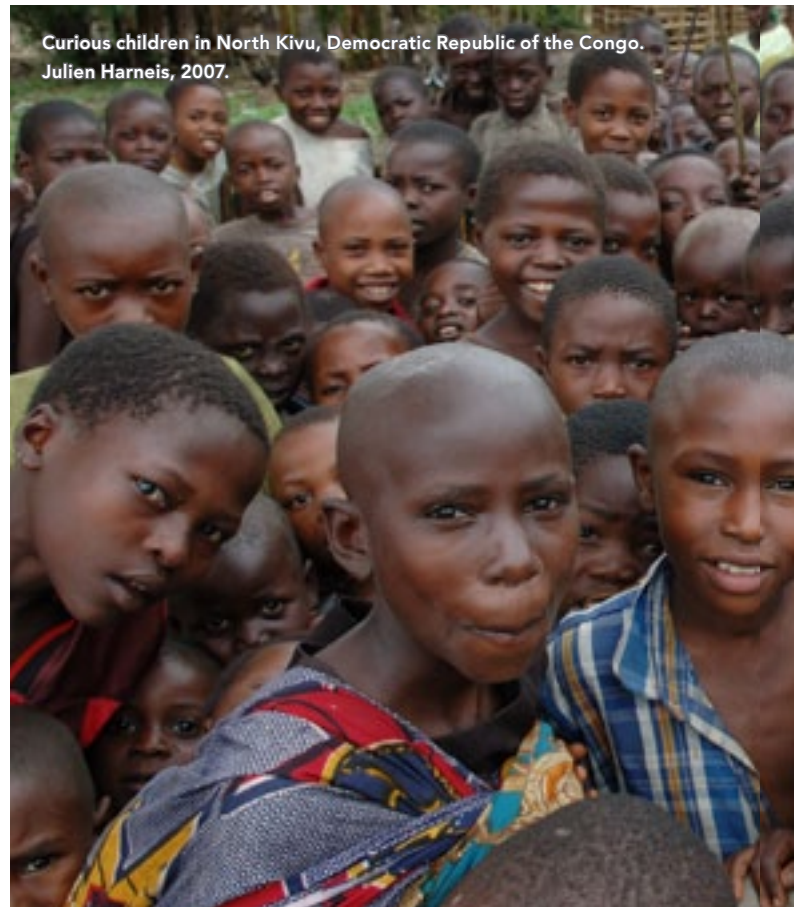
The Orphan Drug Act, first passed in 1983, was created in response to the lack of availability of orphan drugs, which are drugs that treat rare diseases affecting less than 200,000 people, which in turn means R&D is generally neglected.⁵ In an effort to stimulate research and development of these drugs, this proposed program offers incentives that increase financial returns for pharmaceutical companies that

Abstract

The need for innovation and coordination of research and development for globally prevalent diseases has been recognized by the World Health Organization as a primary concern on the global health agenda. Three submissions to the WHO Consultative Expert Working Group that address challenges in this area are the Priority Review Voucher (PRV), Orphan Drug Act (ODA), and Regulatory Harmonization proposals. The PRV and ODA proposals offer incentives for innovation related to neglected disease treatments by providing expedited review vouchers and a period of market exclusivity, respectively. Regulatory harmonization coordinates international drug development through the enactment of universal regulation and standards. Together, these proposals target incentive and coordination mechanisms, but they fail to address the delivery of medicines. Therefore, to achieve the overarching goal of reducing global disease burden, an implementation mechanism is needed to further support access to developed medicines.

target rare diseases. ODA incentives include federal tax credits for up to 50% of costs associated with human clinical trials, a seven-year period of market exclusivity, and the waiving of fees on orphan drug approval.⁶ Of these incentives, the seven-year market exclusivity has shown to be the most appealing to pharmaceutical companies.⁷ This period of market monopoly prevents regulatory restrictions on the price set for the product, and prevents generic drugs from possibly competing with sales. However, in order for firms to take advantage of this incentive, the holder must “assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease.”⁸ The purpose of this clause is to ensure that the innovating drug firm is able to meet the demand for the new orphan drug. In general, the ODA aims to address one of the many needs in the global campaign to improve innovation of medical therapies for orphan diseases.

Since its launch, the ODA has been successful in stimulating the research and development of orphan drugs. Whereas only 10 orphan drugs were marketed a decade prior to its enactment, since its passage, more than 200 orphan drugs have been approved by the FDA.⁵ High costs and small profit margins have been the two main deterrents preventing pharmaceutical companies from investing in orphan drugs. The ODA addresses these issues by providing patent rights to manufacturing firms, which ensure drug firms reap the rewards for their investment in orphan drugs. This is of substantial benefit to firms, as many drug compounds are not normally patentable because they are common chemicals or previously expired patents. Such disincentives prevent pharmaceutical companies from researching known compounds that may have the potential to be applied in new ways to treat rare diseases. The ODA also provides an element of protocol assistance during the research stages, which could be advantageous to drug firms in that they are provided with free scientific advice in regards to their drug’s “quality, safety and efficacy”. Protocol assistance can help drug firms manage their resources more wisely, and help speed



the approval process.⁹ Consequently, the incentives provided under the ODA help improve the R&D of orphan drugs.

In terms of its political attractiveness, subsidization of R&D, market exclusivity and protocol assistance have engendered support from pharmaceutical companies for the ODA. Key stakeholders such as WHO will likely also support the implementation of the proposal as it encourages innovation of drugs that target rare diseases without external funding. However, the resulting high drug costs and potential for shortages has angered taxpayers who subsidize the program. Some taxpayers feel it is unfair that they are subsidizing the R&D costs for pharmaceutical companies while patients continue to suffer due to high out-of-pocket expenses. U.S. public opinion polls have found that 79% of Americans felt that the cost of prescription drugs was unreasonable, and a result of drug firms seeking high profits.^{10,11} Similarly, doctors and patient advocacy



groups have reservations about the market exclusivity available to pharmaceutical companies. They argue that drug firms could reap excessive profits through market exclusivity. These concerns are supported by the fact that, in 2008, the average orphan drug made \$470 million in sales. Blockbuster orphan drugs such as statins have seen revenues as high as \$25 billion.^{10,12} As a result, it seems that although the proposal is politically attractive to pharmaceutical companies and WHO, taxpayers subsidizing the proposal may be opposed.

Past implementation of the ODA in countries such as the United States and Japan indicate that the proposal is operationally feasible, but there may be some concerns in terms of financial feasibility. The ODA may be difficult to implement in “tax haven” regions where the public pays little or no taxes, or in regions where there is little public support for lucrative pharmaceutical companies. Though potentially profitable, implementation of the ODA

could be a double-edged sword for drug firms as well. While the “winner takes all” model secures the victor’s ability to market its drug free of competition, for competing drug firms it could result in wasted time and resources developing a similar drug. Therefore, market exclusivity creates a monopoly, which discourages other drug firms from working on developing the same orphan drugs.¹⁰ Consequently, although past examples have shown that the ODA is operationally feasible, there may be some concerns in terms of its financial feasibility.

Priority Review Vouchers

The PRV system is an incentive program that aims to increase research and development for treatments of NTDs.¹³ If a pharmaceutical company receives FDA approval for a NTD treatment, they can be rewarded with a voucher for an expedited review decision of another drug. PRV holders have the ability to sell or transfer the voucher to other parties.³ This proposal was passed by the U.S. Congress in 2007 and has recently been suggested for implementation in the European Union.¹³ If WHO were to support this proposal, it might encourage multinational drug agencies to prioritize NTDs.

The PRV proposal values innovation and originality by limiting PRV eligibility to treatments that encompass entirely novel ingredients.³ As a “pull” mechanism where the prize for successful research investment outputs is an expedited review, the PRV program could address known limitations of the current global health architecture.¹³ Therefore, the PRV system could facilitate greater coordination among public and private stakeholders and prioritize the innovation of treatments for NTDs. However, the originality provision of the proposal might deter companies. If an adversary’s drug gets approved first, another company’s treatment using the same ingredient would not be eligible. Therefore, their investment might be squandered, meaning investing in R&D for NTDs could pose a financial risk for pharmaceutical companies.¹⁵



Public sector authorities, such as the FDA, may view the PRV as an attractive pull mechanism. Any extra resources or costs needed by the FDA to carry out the priority review are provided through a user fee paid by the voucher holder.³ Therefore, this legislation does not include financial input from taxpayers. The voucher is also an attractive incentive for large pharmaceutical companies. Recent estimates have appraised the potential value for the PRV as high as \$300 million due to the increased market time and exclusivity that it could provide.¹² Therefore, the user cost would be minimal in comparison to the potential profit of an earlier time to market.¹⁶ Smaller biotechnology companies could also offset costs of investing in treatment for a NTD through the sale of a voucher.¹⁷ Moreover, it would be advantageous to

consumers with neglected diseases who could benefit from receiving drugs and vaccines earlier through a priority review.¹³ This proposal may be politically attractive as it retains regulatory control within the FDA, provides pharmaceutical companies with a potentially profitable voucher, and is not dependent on taxpayer funds.

Additionally the market-driven nature of vouchers makes it difficult to estimate their true value. Many of the high-value estimates of vouchers are based on projections of the sales of blockbuster drugs, whereas the actual value of a voucher has been seen to be product-specific. Other variables such as the likelihood of being granted a priority review without a voucher and the profit from an earlier time to market, also affect the value of a voucher.

Furthermore, only one voucher (distributed in 2009 to Novartis) has been issued.¹⁷ In early 2011, Novartis redeemed its voucher for an expedited review of its canakinumab treatment, but the FDA did not approve the drug.^{18,19} This experience demonstrates the uncertainty associated with the voucher's incentive value, since in Novartis' case the use of the voucher did not result in a profitable earlier time to market. However, one lesson from this incident is that the FDA was able to honour the voucher's six-month review target, an accomplishment that could dull the impact of a disappointing review decision.¹⁸

In terms of operational feasibility, there have been concerns over whether quicker reviews lead to a decrease in good regulatory practices and increased safety risks.⁴ However, the proposal only ensures an expedited decision on approval status – not approval in itself.¹³ Therefore, it is up to the FDA to ensure that the six-month target is achievable and that it follows the proper reviewing standards. The proposal includes two provisions as preventative measures against the delay of non-priority drug reviews: the additional user fee paid by the holder and the 365 days advance notice that the holder must give to the FDA before voucher use.³ Overall, this proposal appears to be both operationally and financially feasible since it would not require additional funding from taxpayers or governing bodies, and because an expedited review has been determined to be achievable.

A major concern of this proposal is that it does not address implementation of the therapy after a PRV has been rewarded. If new effective drugs are developed but not administered, then the ultimate goal of treating people with NTDs will not be met.

Regulatory Harmonization

In general, regulatory harmonization encompasses any reform aimed at improving current efforts in foreign aid through increased coordination of global health actors. This definition encompasses a broad range of operations, which limits this proposal's capacity for thorough analysis. To provide a more

focused and relevant analysis, the critique will look specifically at the harmonization of international pharmaceutical regulations through: (1) development of universal procedures for research, development and approval; (2) streamlining of procedures to reduce their burden on international governments and agencies; and (3) improving systems of information sharing between global actors.^{20,21} Globalization has increased the number of actors and initiatives within the global health domain.²² Due to a lack of coordination and collaboration, R&D efforts have been fragmented and overlapping. As a result, despite an increase in pharmaceutical resources and funding, there have been decreasing annual numbers of new active substance approvals.²³ Also contributing to this trend is the duplication of research and regulatory impediments to approval.²⁴ Harmonization aims to reduce these obstacles by streamlining and standardizing processes within the international pharmaceutical development sector.^{21,25}

Regulatory harmonization strengthens the system by which pharmaceuticals are developed for public use.²⁶ The discord between national drug regulatory agencies has resulted in repetitive processes, redundant paperwork, and large scale wasting of resources. The accomplishments of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) provide a model of the potential benefits of regulation. The ICH is a collaboration between the U.S., Europe and Japan. It was conceived following the WHO Conference of Drug Regulatory Authorities in 1989 to address weaknesses in the global pharmaceutical sector through improving coordination and communication, and reducing overlap.²⁵ Since 1989, the ICH has encouraged reform through international dialogue and has developed multi-national standardized institutions to replace the current incompatible systems of drug approval and registry. States that have employed these standardized processes have been able to significantly reduce the burdens of drug development on governments and agencies. As such, international collaboration could





promote more timely and economical market entry of drugs, thereby reducing the consumer price of the drug.^{25,27} Therefore, regulatory harmonization involves system strengthening and coordination of pharmaceutical R&D, but does not encourage innovation of medicines.

Regulatory harmonization can be attractive for many countries as it has the potential to reduce the time and funding required to obtain drug approval, thereby increasing a drug's long-term profitability. If the establishment of international standards is complemented with a commitment to provide resources for development, developing nations could find this proposal particularly politically attractive. This has been observed in Japan, which has experienced significant pharmaceutical sector growth through their assisted compliance with ICH's international standards.^{21,27,28} Overall this promotes international market expansion and increases the availability of medicines. By increasing supply and decreasing administrative costs, harmonization can increase consumer affordability and improve international health access.²⁹ However, regulatory harmonization is solely a mechanism for improving access through system strengthening, and does not address other factors which influence access, such as financing and delivery. As coordination seeks to reduce drug prices, it is unattractive to pharmaceutical companies whose compliance may be necessary for successful reform. Accordingly, regulatory harmonization should be paired with incentivizing mechanisms to promote the participation of pharmaceutical companies under these regulations. If it is not paired with incentivizing mechanisms it may be politically attractive to international institutions and states, but not to pharmaceutical companies.

Though regulatory harmonization of pharmaceutical development has many advantages, there are concerns regarding its implementation. First, though rapid market entry of new drugs can be economically beneficial, it has the potential to compromise safety and undermine older and cheaper drugs with reliable safety profiles.³⁰ Therefore,

quality assurance must be a central focus of the system. Additionally, if developing countries cannot meet universal standards, the negative impact of withdrawing these medicines may be more dramatic than the risk associated with failing to achieve international standards.^{29,30} To circumvent these potential negative impacts, there must be proper support programs available.²⁵ As seen through the example of the ICH, regulatory harmonization can be operationally feasible, but the incorporation of local support programs would enhance its effectiveness.

In general, it is difficult to comment on the financial feasibility of regulatory harmonization due to the vagueness of the proposal. Though operational feasibility lends support for this proposal, the financial uncertainties represent a challenge in determining whether the potential benefits of the proposal outweigh any financial costs.

Future Recommendations

The pharmaceutical market is governed by both competition and coordination between participating actors, but no standards exist describing the ideal balance of these dynamics. Proposals for reform can be placed on a spectrum where programs promoting total coordination stand at one extreme, and those that strive for total competition at the other. The PRV and ODA programs rely on market-driven incentives to facilitate innovation and diversity. As such, it appears that the PRV and ODA proposals would fall more toward competition on this spectrum and only slightly on the periphery of coordination. Integrating regulatory harmonization, which falls closer to the coordination end, could ameliorate this weakness by establishing universal protocols, which would coordinate international drug development.

In improving global access to medicines, the WHO cites four key aspects in need of attention: (1) rational selection of the medicines for the public; (2) reliable health and supply systems; (3) affordable prices for those medicines; and (4) sustainable financing of health care and medicines.²⁹

The PRV and ODA proposals address the first key aspect by promoting development of drugs targeting neglected diseases. On the other hand, regulatory harmonization is involved in providing reliable health and supply systems. Regulatory harmonization also has the potential to increase affordability of drugs. However, all three proposals neglect considerations for sustainable financing of health care and medicines. In general, all three proposals also fail to address delivery arrangements or implementation for increased access to medicine. Therefore, these programs would need to be accompanied by a delivery mechanism to achieve the socially desirable outcome of minimizing the effects of NTDs (see Table 1).

A possible method to address delivery concerns could be through the incorporation of the “Access of Medicine Index” (AMI) into the PRV and

ODA proposals. The AMI ranks companies based on their effort to increase access to medicine for communities in need.³¹ A provision of the PRV and ODA could be that companies need to meet a defined standard on the index in order to receive and benefit from tax credits and vouchers. An appropriate regulatory body (i.e. FDA) could determine the cut-off in conjunction with the Access to Medicine Foundation. The integration of a measure such as the AMI would be a necessary step towards considering the accessibility and delivery of medicines. However, employment of such a measure may include feasibility and operational barriers that would need to be considered.

A concern of the regulatory harmonization proposal is its cultural sensitivity when considering the impact of universal standards on developing countries. Currently, the U.S., European Union and



Indian boy selling food on roadside. Graeme Hoit, 2011.



Japan – as founding members of ICH – have had the greatest input in directing the harmonization of pharmaceutical standards. This prevents the proposal from being sensitive to countries of various political and economic characteristics, thereby limiting its international applicability. This has been identified as an area WHO can improve upon as the global coordinating authority for international health. In future, international regulatory bodies should be mindful of the needs and resources of different countries when establishing standards.

Conclusion

The combination of these three proposals could form an efficacious and mutually beneficial partnership. Firstly, the PRV and ODA systems facilitate the competition of ideas, which allows for overlap of drug development and thus does not coordinate action. In contrast, regulatory harmonization encourages the organization of action by establishing universal standards and regulations. If the three proposals were combined to work in conjunction with one another, or with other proposals, they may strike a balance between the competition of ideas and the coordination of action. Consequently, if WHO were to support these three proposals they could make considerable strides towards finally achieving the Millennium Development Goals.

Actionable Key Messages

- ⇒ Pairing the PRV and ODA proposals could effectively address the need for incentives for treatments of both neglected and tropical diseases.
- ⇒ The PRV system could encourage innovation for NTDs, but its novelty makes appraisal of the voucher's value a difficult task.
- ⇒ In order to maintain public support for R&D subsidization under the ODA, a limit may need to be placed on the amount of profit drug firms can make under the seven-year market exclusivity.
- ⇒ Regulatory Harmonization could present a viable option for reducing obstacles to manufacturing affordable medicines, however, supports must be available to developing countries to aid in their fulfilment of new international regulations.
- ⇒ The PRV, ODA and regulatory harmonization systems do not address delivery of medicines and must be complemented by an implementation mechanism to ensure accessibility to drugs.

Table 1: Summary of the Three Proposals

	ODA	PRV	Regulatory Harmonization
Pharmaceutical R&D			
Does the proposal encourage innovation?	Yes	Yes	No
Does the proposal facilitate coordination?	No	No	Yes
Is the proposal politically attractive?	Somewhat - may receive opposition from taxpayers	Yes	Somewhat - may be unattractive for pharmaceutical companies
Implementation Considerations			
Is the proposal operationally feasible?	Yes	Yes	Yes
Is the proposal financially feasible?	Somewhat - may be difficult to implement in "tax haven" regions	Yes	Unclear

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Girl drifting through the Ganges River. Graeme Hoit, 2011.

Chapter 3

Product Development Partnerships, Tax Breaks and Green Intellectual Property

Derek Chan, Won Yong Choi and Ariela Rozenek

Status Quo

Barriers for R&D in Neglected Diseases

Ten million people die each year because they lack access to medicines.¹ Innovative strategies to finance research and development (R&D) for neglected tropical diseases (NTDs) that engage the expertise of pharmaceutical industries and key stakeholders are required to address these inequities.² The lack of knowledge needed to tackle the “diseases of the poor” is the most significant obstacle to access to medicines.³ However, drug discovery is not the major bottleneck. Since returns on investment cannot be guaranteed, pharmaceutical R&D firms are reluctant to invest in the development of drugs to treat NTDs.⁴

Researchers presenting competitive grant applications aligned with national interests often receive public funding.² However, such one-time grants are not congruent with the lengthy process of drug development.^{2,5} Considering the limited and uncertain markets in low-income countries, R&D investment is often not forthcoming given it provides insufficient commercial returns.⁶ Current financing mechanisms do not provide enough incentives to overcome the scientific and commercial risk that companies face when developing medicines for low-income countries.^{2,6}

The strengthened intellectual property (IP) environment engendered by the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement only supports R&D incentives for commercially attractive products.⁶ TRIPS flexibilities aim to encourage access to medicines in low-income countries.^{5,7} However, these provisions erode patent rights and further deteriorate market capabilities in low-income countries.^{5,6,8}

Cumulatively, these circumstances contribute to the “10/90 gap” in R&D financing for NTDs, whereby 10% of financial investment in R&D is spent to treat 90% of the world’s population.^{2,9} This reality translates to insufficient funding to treat illnesses that predominantly affect low-income countries.

Abstract

Providing universal access to medicines is a challenge that warrants a robust and effectively-implemented global financing system. Pooled Funds for Product Development Partnerships, Tax Breaks and Grants, and Green Intellectual Property are three proposals that have attempted to address this funding gap and have recently gained considerable attention. Using an analytical framework developed from criteria outlined by the World Health Organization’s Consultative Expert Working Group on Research and Development (CEWG) and by external policy reviewers, each proposal was cross-evaluated with an evidence-based approach. Although no single proposal clearly satisfied a majority of the set criteria, integrating important functions outlined in each would yield the fiscal leverage needed to support the overarching cause. The recommended combination of bond financing, partial portfolio management and external audits was discussed according to gains and losses. Further potential for synergizing this mechanism with other proposals currently being considered by the CEWG was also explored.

Current Financing Mechanisms

R&D for medicines is currently both publicly funded from research councils and privately funded from a combination of shareholder equities in pharmaceutical companies and internally generated revenues.²

Product development partnerships (PDPs) leverage private investments to direct R&D focus towards NTDs.⁶ PDPs knit together public sector funding and private sector resources, directing both towards a common goal.⁶ PDPs result in quicker, less costly developments of technologies with better public health benefits.⁶

Tax credits for R&D in NTDs also contribute to the current global health financing system. By reducing the cost of R&D for pharmaceutical companies, these tax credits encourage greater private sector involvement.^{10,11} However, these initiatives fail to provide substantial incentives for companies to focus on R&D for NTDs.¹¹

Three Financing Proposals

The following three proposals for access to medicines reform attempt to address current financing gaps for R&D on NTDs, and have attracted considerable attention given the current global political prioritization of access to medicines.

Pooled Funding for Product Development Partnerships

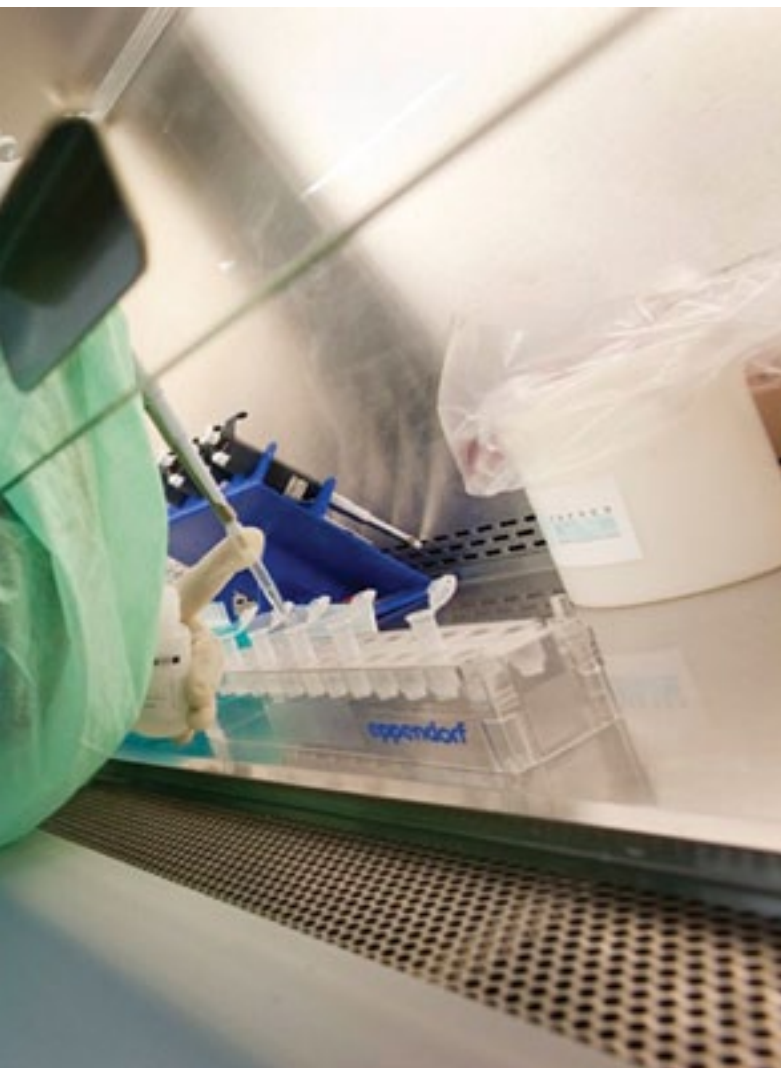
A. Product Development Partnership – Financing Facility (PDP-FF)

This mechanism proposes a bond-financed pooled fund to support long-term PDP development in R&D for NTDs.¹² Legally-binding commitments made by donor countries and private entities with high credit ratings would repay bondholders in the event of financial shortfalls. These commitments



allow bonds to be issued by multilateral development banks on international capital markets, relaying proceeds to finance PDP activities.¹² Three revenue streams are proposed to promote sustainable self-financing of this finance facility:

- 1. Royalties:** Usage-based payments are negotiated between PDPs and product production firms in both high- and middle-income countries.
- 2. Premiums:** Fees incurred on sales for a certain period after launch are paid for by purchasers in low-income countries supplemented by donor contributions to offset high costs.
- 3. Grants:** Subsidies from donors are separate from the PDP-FF model, but are implemented in alignment with PDP-FF to help meet the long-term financing needs of PDPs.



B. Industry R&D Facilitation Fund (IRFF)

Alternatively, a separate pooled fund could be created to finance PDPs with approved plans for R&D in NTDs.¹³ Donors would invest in a portfolio of PDPs, making these industry R&D facilitation funds a central financial hub that could potentially take on additional coordination of shared services such as legal services and human resources.¹⁴ Recipients of funding from these facilitation funds must initially meet strict eligibility criteria and pass periodic progress reviews to receive continued support.¹³

Industry R&D facilitation funds commit to a PDP funding ceiling for five years

based on equivalent donor commitments. Ideally, PDPs with approved financing plans would receive reimbursements for 80% of expenditures, strengthening product development initiatives.¹⁴ Industry R&D facilitation funds ultimately aim to lead to better PDP outcomes that feed back to encourage more industry deals for R&D in NTDs.¹³

C. Fund for Research in Neglected Diseases

Another proposal is to create a pooled fund specific to R&D for NTDs, applying portfolio management techniques to allocate funds on a milestone-to-milestone approach to select the best drugs for NTDs.¹⁵ University-based institutions, biopharmaceutical companies and PDPs that have fully developed a final product with the support of such a fund can donate their exclusive IP to the fund's licence pool, but this component is currently being reconsidered.¹⁴ Another amendment proposes shifting this funding approach towards a "partial portfolio management system" that funds only the expensive later stages of R&D.¹⁴

Tax Breaks and Grants

The coupling of tax breaks and grants is proposed to incentivize R&D for NTDs. Three countries currently implement global health-oriented tax incentives.¹⁰ Tax breaks generally refer to tax deductions or refundable credits provided by governments after processing the company's claim on R&D expenditures. Despite the advantage of tax credits in reducing upfront research costs, there is little participation in tax break programs due to administrative burdens and delayed payments.¹⁰ Providing grants in the initial phases of research with tax credits could offer additional incentives, improving the current financing system for R&D in NTDs.¹⁰



Green Intellectual Property (Green IP)

Green Intellectual Property is proposed to encourage the development and distribution of essential medicines for low-income countries. Green IP diverts part of the patent-related monetary flow toward a Trust Fund.^{7,16,17} Under this scheme a compulsory tax is collected at three stages: 1) assurance premiums on patent applicants; 2) patent owners; and 3) an allocation of fees collected by patent offices.¹⁶ This proposal calls for two distinct mechanisms of financing: aid and insurance. Green IP aid aims to finance access to technologies by providing grants to countries for costly patent licences and to organizations for direct drug purchases.² By subsidizing the cost of the licensing fee, Green IP insurance allows for the non-commercial transfer of patents from pharmaceutical companies to users unable to access technologies due to lack of capital.¹⁷

Proposal Assessment

A common analytical framework was developed and systematically applied to the three proposals.

Resource Mobilization

A. Inovativeness

Funding from national governments and international organizations is essential but insufficient for access to medicines.⁴ Among the proposals, PDP financing facilities offers the most innovative source of funding by tapping into capital markets through bond issuances offered by a multilateral development bank.¹² Like financing facilities, Green IP draws on a new market to fund a trust to finance R&D for NTDs. Green IP also introduces a new “tax” that innovatively draws on the monetary flow of the global IP system.^{18,19} However, this tax is compulsory, whereas PDP financing facilities remain optional, while providing sufficient incentives for donor participation.

Funds for NTD research and industry R&D finance facilitation assume that existing donors are attracted to pooled funds and propose to essentially maintain the status quo. However, recent stakeholder dialogues reveal that donors with previous experience are less likely to participate in pooled funds and risk diluting their decision-making power.¹⁴ Similarly, the tax breaks and grants proposal offers little innovation, since the latter merely couples two existing R&D funding mechanisms.¹⁰

B. Diversity and Flexibility

PDP financing facilities provide the most diverse funding options through donor guarantees, royalties and premiums. The responsibility of handling invested funds is shared, diluting the risk of depending on a few donors. The opportunistic basis to which donors are able to commit funds for a short period of time also makes this mechanism attractive.¹⁴

Industry R&D facilitation funds, funds for NTD research, and tax breaks and grants only offer somewhat diverse and flexible resources given that these proposals suggest drawing funds from existing and new public-private donors.^{18,20} Green IP taxes are flexible and can be adjusted to local contexts to promote dependable funding and encourage participation among low-income countries.²¹ However, all three Green IP taxes draw from the same market, significantly limiting the diversity of funding sources.

C. Specificity for R&D in NTDs

PDP financing facilities and Green IP mobilize a new group of sources to fund R&D for NTDs. Projections suggest that financing facilities could raise \$2.2 to \$6.9 billion USD in 30 years,¹⁴ whereas Green IP is projected to amass \$50 billion USD annually allowing for considerable additionality.¹⁶

Industry R&D facilitation funds and funds for NTD research offer little additionality to the resource-generating nexus other than increasing funding through pooled resources.¹³ Similarly, tax

breaks and grants offer little beyond the prospect of attracting new participants.¹¹

D. Quantity and Additionality

Allocation and governance measures within PDP financing facilities, facilitation funds, and funds for NTD research are designed and implemented to specifically fund R&D for NTDs.¹⁴

In contrast, tax breaks and Green IP do not guarantee that full proceeds would be directed to R&D for NTDs since they are marked for R&D expenditures in general, and a wide range of “eco-socio patents” respectively.^{7,11} Generally, funds raised from direct and compulsory taxes are unlikely to be allocated to R&D for NTDs.^{18,22}

Cost-Effectiveness

Establishment of all five models requires upfront and ongoing costs, resulting in varying potential impacts on R&D for NTDs. Among pooled funds, industry R&D facilitation funds is the most cost-effective since it requires the least investment.¹³ Tax breaks and grants also have low management costs since companies pay their own administrative fees to claim tax incentives.²⁰ However, the proposed amendments offered by tax breaks and grants are inadequate to improve the status quo since their current implementation has experienced low uptake with little positive impact.¹⁰

Based on the expenditure of the International Finance Facility for Immunization that works on similar principles as the proposed PDP financing facility for NTD research, projected initial expenses for this latter model are substantial, ranging from low to modest depending on bond issuance costs.^{14,19} However, the model projects significant long-term revenue,¹² making financing facilities somewhat cost-effective. Funds for NTD research would also incur significant costs due to their milestone-to-milestone funding allocation strategy. The proposal’s emphasis on central oversight and monitoring incurs a higher investment cost relative to both PDP financing facilities and industry R&D facilitation funds, but



the outcome can lead to greater health impact.¹⁴ The centralized structure of the proposed Green IP Trust Fund also requires significant upfront and ongoing investment costs since tax introductions require legal changes and consistent regulations to ensure compliance.¹⁸

Predictability and Sustainability

Predictable and sustainable financing mechanisms are imperative to stimulate both early-stage discovery and to ensure late-stage development of essential medicines.²³ PDP financing facilities are designed to be self-sufficient once established, attracting supporters of sustainability. Front-loaded funding for 10-15 years through bonds and donors allows low-income countries and PDPs to plan longitudinally knowing the exact availability of resources. Since bond issuances can also be timed to fit the needs of the product development process, PDP financing facilities significantly improve current fragmented and short-sighted funding practices.¹⁴ Green IP's funding scheme relies on taxation which is both financially sustainable and relatively predictable.⁹ Taxes are not likely impacted by economic downturns, or at least not as much as optional donations.⁷ In the last global financial crisis, nine new countries signed on to UNITAID's airline tax to finance access to medicines initiatives.^{19,21} However, there is only moderate certainty over revenue forecasts since actual revenues will depend on providers' and consumers' responses to the new tax.³

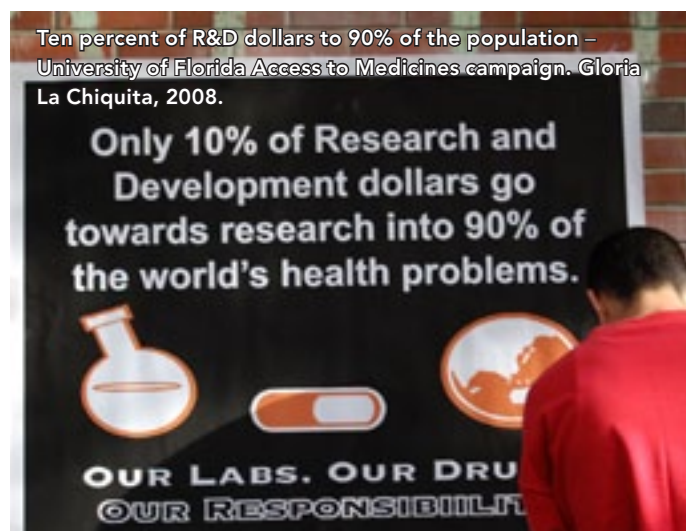
A fund for NTD research would also offer reasonable predictability measures since portfolio management teams allocate funds according to promising project prospects.¹⁵ Grants are not offered longitudinally, limiting the long-term funding predictability.^{24,25} Tax breaks offer little predictability since they are given based on reported company expenditures.²⁰ Industry R&D facilitation funds only increases predictability by planning a five-year budget ceiling for PDPs with legally-binding commitments from donors.¹³ Since there are no other

guarantors, the overall predictability of this last model is relatively low.

Governance Structure

Global financing mechanisms require robust governance structures that are centrally operated to effectively manage and allocate resources.^{14,26} Financing facilities, facilitation funds, and funds for NTD research all align with these goals by employing small governing bodies to avoid high implementation costs.¹⁴ PDP facilitation funds employ a secretariat and various staff to share the tasks of managing loans, disbursing funds to PDPs, monitoring progress and reporting to donors. A governing board comprised of PDP representatives, donors and independent experts directs where funds are allocated.¹² Similarly, industry R&D facilitation funds have a small management team with an advisory board comprised of experts in R&D for NTDs and financial knowledge.¹³ Funds for NTD research would likely use a portfolio management team and an overarching board that consists mostly of donor representatives that define the strategy for disease and product scope.¹⁵ Overall, each of these structures is feasible; however, the proposed details require further thought to justify the varying proportion of representatives that comprise each governing body.

Like the pooled fund models, the Green IP Trust Fund would be managed by a central authority.



This management body provides leadership and coordination of all operations.¹⁷ However, the proposal fails to provide direction for appropriate governance structures within the management body. Tax breaks and grants also do not feature a formalized governance structure.²⁰

Portfolio Management

Additional funding of at least \$1 billion USD annually is needed over the next decade to fund R&D for NTDs.²⁷ Therefore, wisely allocating available funds to the most promising projects is a critical step.²⁷ A unique component of funds for NTD research is the milestone-to-milestone funding approach based on medical and scientific criteria. The “partial portfolio management” strategy allows innovation during early stages of R&D and optimizes fund allocation.¹⁴ These strategies ensure that only promising projects are funded and monetary resources are not wasted. Similarly, Green IP ensures that funds are allocated only to projects with the greatest need based on attempted IP negotiations between patent users and holders to encourage affordable transfers of technology.⁷ Funds for NTD research and Green IP feature extensive portfolio allocation provisions. However, Green IP lacks the specific designation of experts assigned to assess proposals and allocate funds, which is likely to be found in funds for NTD research.

Grants are allocated to projects with the greatest potential for innovation.^{28,29} Unlike the proposed funds for NTD research, the allocation assessment

process for grants is not uniform, and subject to personal biases.^{18,30} Industry R&D facilitation funds and PDP financing facilities would also oversee funding allocations to PDPs according to donor agreements, but do not seek to manage these projects any further to ensure the health impact or feasibility of delivery in low-income countries. These two models assume that PDPs have developed the correct structures to manage their own projects well, but this assumption may not be accurate.¹⁴

Intellectual Property Policies

Working within the patent system is a reality all proposals should account for because IP rights should not impede access to medicines.^{8,15} Maintaining IP rights is evident in the proposed Green IP allocation process. The suggested system plans to avoid further erosion of patent rights and the continued deterioration of market capabilities in low-income countries by leveraging IP rights to encourage access to medicines.^{5,7}

Within the pooled funding models, PDP financing facilities and industry R&D facilitation funds leave IP management to PDPs. Funds for NTD research uniquely proposes exclusive licensing of the developed technology; if the technology is used for other applications, the patent holders would pay a royalty back to the fund, somewhat diluting the PDP’s right to IP. Currently, proponents of funds for NTD research are reconsidering this policy.¹⁵

Tax breaks and grants suggest further dilution of IP rights to encourage access to medicines in

Pharmaceutical research and development for neglected diseases. Novartis AG, 2009.





Rapid HIV testing in Marondera, Zimbabwe. UK Department for International Development, 2009.

low-income countries.³ Grant contracts offered to pharmaceutical companies stipulate that knowledge generated with granted funding becomes the property of the granting organization either exclusively²⁸ or partially.²⁴ This IP policy nullifies the incentives offered by tax breaks and grants.¹⁵

Economic and Political Feasibility

Global health policies must be politically appealing and economically feasible in order to be effectively implemented.³¹ The minimal start-up costs and changes in status quo for pharmaceutical companies within tax breaks and grants renders the proposal both politically and economically feasible.^{10,31} Since the most recent WHO Regional Office for Africa (AFRO) consultation meeting concluded that a multilateral development bank like the African Development Bank has the capacity to act as a financial intermediary for issuing bonds,²² bond financing in PDP-FF is also feasible. This model de-links the costs incurred at the R&D stage from

the price of the product. However, politicians are increasingly sceptical about the prospects of external financial engineering in light of the recent global financial crisis, detracting from financing facilities' overall economic feasibility.¹⁴

Funds for NTD research and industry R&D facilitation funds are less likely to appeal to stakeholders given the limited incentive for major investors to participate in pooled funds. Politicians may be dissuaded from implementing these systems since mostly small, inexperienced donors are attracted to pooled funds.^{14,32} Political priorities may also diverge from wanting to invest in R&D for NTDs.¹⁴

Green IP's novel and complex system detracts most from the political and economic appeal of the proposal. In general, new taxes are politically unfavourable¹³ and unlikely to generate popular support.¹³ Low-income countries may not be able to sustain the introduction of a complex novel financing mechanism.²² Overall, the combined disruption to the status quo and lack of political motivation renders this proposal highly unfavourable.





Transparency and Accountability

The integrity of any financing system is crucial, especially when the end results relate to health impact.³³ In both the pooled fund models and Green IP, accountability may be diluted when the donor-product developer relationship is separated by a large intermediary fund.³⁴ PDP financing facilities and industry R&D facilitation funds attempt to ensure transparency and accountability within their financial processes; however the same remains implicit in funds for NTD research.¹⁵ In PDP financing facilities, a secretariat tracks PDP progress and financial operations, reporting information to donors as well as the public.¹² Financial operations are also subject to regular independent audits. In industry R&D facilitation funds, the advisory board assumes an accountability role, while accredited PDPs are expected to produce yearly audited accounts.¹³

Proposals for Green IP recommend that a new third party aligned to the World Trade Organization (WTO) should manage the Trust Fund.¹⁶ The provisions mandated by the WTO to ensure transparency and accountability are limited and unlikely to translate into the complex structure envisioned in Green IP proposals.³⁵ Tax breaks and grants also do not feature structures to ensure transparency in funding allocation and fund management. The broad eligibility criteria for tax breaks hinder the governing body's ability to identify fraudulent claims.³⁶

Conclusion

Choosing to establish an ideal financing system to help increase access to medicines is difficult given the numerous and complex factors warranting careful consideration. The integration of bond financing outlined in PDP financing facilities, partial portfolio management built from funds for NTD research, and external audits for accountability purposes brings together the necessary elements for a financing system structured to satisfy the following criteria: resource mobilization, cost-effectiveness, predictability and sustainability, governance structure, portfolio management, IP policies, economic and political feasibility, and transparency and accountability. Tax breaks and grants, as well as Green IP, lack many integral components that lend to economical and political feasibility.

A few disadvantages exist in such a combined financial mechanism, such as higher projected costs associated with implementing all three elements and lack of incentives for larger and more experienced donors to participate in a pooled fund for R&D in NTDs. Synergizing the recommended integration of financing elements with the Health Impact Fund proposal could bridge many of these obstacles. The Health Impact Fund would complement the PDP financing model by supplementing inadequate or uncertain funding. The rewards envisioned by the Health Impact Fund proposal could be reinvested in future projects by public partners and



A polio vaccine campaign. PATH, 2010.

incentivize major private donors to invest more in R&D through PDPs and pooled funds. The Health Impact Fund idea also complements the recommended funding mechanism and further lends to its predictability by allowing revenues to be based on registered drugs. Additionally, this mechanism could act to monitor prices and licensing agreements. Finally, the Health Impact Fund proposal motivates the distribution of successfully developed products and furthers the breadth of health impact, fulfilling a perpetually lacking component in all assessed financing proposals.³⁷

Key Messages

- ⇒ Increasing access to medicines is a challenge that must incorporate an innovative financing system that guarantees returns on investments in R&D for NTDs.
- ⇒ An integrated model featuring bond financing, partial portfolio management and external audits would best address gaps in the current global financing system.
- ⇒ Synergy with the Health Impact Fund proposal could complement gaps in attracting major donors, assessing impact, distributing medicines and strengthening health systems that finances alone fail to address.

Evaluative Summary

Table 1: Cross-Evaluative Comparison of All Proposals

	Pooled Funds for PDPs			Tax Breaks & Grants	Green IP
	PDP-FF	IRFF	FRIND		
Resource Mobilization					
Innovativeness					
Diversity and Flexibility					
Quantity and Additionality					
Specificity for R&D in NTDs					
Cost-Effectiveness					
Predictability and Sustainability					
Governance Structure					
Portfolio Management					
Intellectual Property Policies					
Economic and Political Feasibility					
Transparency and Accountability					
Legend				Excellent; addresses all criteria aims and seeks to improve the status quo Good; addresses some criteria aims and somewhat improves the status quo Neutral; addresses few criteria aims with no foreseeable changes to the status quo Poor; contradicts criteria aims and fails to address gaps in the status quo	

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A crowded waiting room at Lunsar Hospital in Sierra Leone. Mustafa Ozturk for IHH Humanitarian Relief Foundation, 2011.

Chapter 4

Prizes, Advanced Market Commitments and the Health Impact Fund

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Introduction

In 1975, the World Health Assembly introduced the concept of “essential medicines” to the global health community. Although its aim was to address the disparities in access to life-saving drugs around the world, 35 years later, essential medicines remain unaffordable and inaccessible in many developing countries.¹ Today, major barriers to achieving this goal include the lack of R&D into neglected diseases, the affordability of drugs, and their inefficient distribution.¹ Market-based incentives use competition between pharmaceutical companies to promote the creation of affordable drugs for the developing world.² This paper evaluates three market-based incentives – prizes, advanced market commitments (AMCs) and the Health Impact Fund (HIF) – on their capacity to address the concerns of access to medicines.

Prizes

Prizes use monetary rewards to incentivize the creation of drugs for neglected diseases.³ Sponsors establish competitions, offering rewards to developers who can design and execute predefined target products.³ In exchange for accepting prizes, drug developers relinquish their intellectual property (IP).³ This allows for generic manufacture of drugs, which should then reduce prices.⁴ By severing the traditional link between price of a pharmaceutical product and the incentive to innovate, the goal is to stimulate private investment in otherwise non-lucrative fields.⁴ Prizes exist in two variations: end prizes, which are awarded at the final stages of a product’s development, and milestones, which are awarded at intermittent points along the development pathway.³

Advanced Market Commitments

An AMC is a legally-binding financial contract that is made between pharmaceutical developers and funders.⁵ Sponsors of AMCs guarantee the future purchase of drugs that are currently in their

Abstract

Addressing the inaccessibility of essential medicines in the developing world requires a response that promotes research and development for diseases of the developing world, increases the affordability of drugs and improves their distribution. Three market-based incentives – Prize-based Incentives (PBIs), Advanced Market Commitments (AMCs), and the Health Impact Fund (HIF) – were evaluated on their (i) capacity to promote R&D into neglected diseases, (ii) feasibility, and (iii) potential to improve health in the developing world. The HIF struggles with challenges to feasibility, and PBIs seem better suited for less cost-intensive research rather than drug development. While each proposal has its strengths, AMCs appear to offer the most viable solution to access to essential medicines.

developmental stages.⁵ This creates markets that are large and reliable enough to stimulate private investment into neglected diseases.⁵ In exchange, developers agree to supply a set amount of their completed products at a fixed price.⁵ For each AMC, an independent adjudication committee is established to determine if finished products meet a designated product profile.⁶ The costs of AMCs are shouldered mainly by donors (typically developed countries and NGOs), but a smaller “co-pay” is paid by developing countries.⁶ After the initial amount of the vaccine has been delivered and paid for, developers then provide their products to developing countries for a previously negotiated “tail-price.”⁷

Health Impact Fund

The HIF employs an optional pay-for-performance scheme that remunerates developers based on the health impact of their drug.⁸ In electing to register with the HIF, developers are required to sell their products at cost.⁸ In exchange, they receive an annual share of rewards from a fixed pool of money, proportional to their product’s health impact.⁸ To assess these proposals on their ability to address access to medicines, three criteria have been established: 1) the capacity of the proposal to promote R&D into neglected diseases; 2) the feasibility of the proposal; and 3) the proposal’s potential to improve health in low- and middle-income countries.

Promoting R&D in Neglected Diseases

One of the major problems with ensuring access to essential medicines is the scarcity of safe and effective pharmaceutical agents that target neglected diseases.⁹ Currently, only a limited number of compounds for neglected diseases enter early-stage development, and even fewer are translated into finished products.¹⁰ When engaging in pharmaceutical R&D, developers conduct a risk-reward assessment, their goal being to determine whether the gains of pursuing an avenue of development outweigh the costs.^{11,12} Given the high cost of pharmaceutical R&D, the value of the



reward must be large enough to coax developers into investing in R&D for neglected diseases.¹¹ Early-stage development drugs are especially high risk investments due to the low probability that a drug will be brought to market.¹³ To improve access to medicines, proposals must promote R&D in all stages of development.

In recent years, prizes such as Prize4Life and the Global Alliance for TB Drug Development have found success in promoting smaller-scale innovations.^{14,15} However, prizes remain unproven in the context of drug development.⁴ By providing rewards only at the end of the development pathway, end-prizes do little to compensate for the risks of



early-stage R&D.³ Milestone-based prizes address this concern by providing prizes at intermittent points along the development pathway; this type of prize allows investors to funnel prize money back into the R&D process, thereby reducing financial risk.³ Assuming that donors specify the creation of a marketable drug as a prize-requirement, the ability of prizes to create finished products depends on developer participation.⁴ In this respect, milestones, which are more effective at reducing risk in early-stage R&D than end-prizes, would be more likely to garner developer participation.⁴ Where both types of prizes fail, however, is in their ability to promote improvements to existing drugs.³ Once a prize has

been paid and a drug is brought to market, there are no continual incentives to improve upon existing products.^{3,4}

AMCs can be used to stimulate R&D for drugs in all stages of development.⁷ Having been implemented in 2009 for the creation of a pneumococcal vaccine, there is strong evidence to suggest that AMCs are a viable method of bringing drugs for neglected diseases to market.¹⁶ Established between Pfizer, GlaxoSmithKline, a consortium of governments and the Gates Foundation, this AMC resulted in a finished vaccine that has since been distributed throughout many developing countries.¹⁷ However, this product was already in late-stage development,¹⁸ and the ability of AMCs to promote early-stage R&D still remains largely theoretical. AMCs aim to create a market for drugs in their early stages of development by establishing contracts between developers and purchasers.¹⁹ In guaranteeing the purchase of products for neglected diseases, these contracts reduce the risk associated with early-stage R&D and thus promote drug development.¹⁹ Moreover, since an independent adjudication committee will only allow a developer to enter into an AMC if their product is clinically superior to an existing drug,⁷ there are continual incentives for developers to improve upon existing products.

The innovative potential of the HIF lies in its ability to offer lucrative payouts for drugs that would otherwise be unprofitable under the current patent system.⁸ The payouts of the HIF are anticipated to be large enough to generate investment into both early- and late-stage development.⁸ However, the reward mechanism of the HIF divides a fixed pool of funds among the registered products, where developers receive a share of the pool proportional to their product's health impact.⁸ This introduces a significant risk that a "blockbuster" drug such as a malaria vaccine, with an overwhelmingly high health impact, would claim the vast majority of the HIF's reward pool and leave little money for other products.⁸ Like AMCs, the HIF offers continual incentives for firms to improve on existing treatments by rewarding



improvements to drugs that have a greater health impact.⁸

All three proposals rely on large incentives to offset the risk of R&D, but milestone prizes offer the greatest risk reduction to investors by offering intermittent rewards along the drug development pathway. Prizes are not, however, the best proposal because they do little to promote continual innovation. While there are larger risks associated with AMC and the HIF, their system of only rewarding finished products is more likely to result in marketable drugs. A synergy could possibly be found in implementing the AMC or HIF, while including either an intermittent prize mechanism or a start-up research grant to offset early-stage R&D risks.

Feasibility

Operational Feasibility

The operational feasibility of a proposal is determined by the ease with which it can be implemented and the complexity of the governing structures it requires.²⁰ Moreover, to be operationally feasible the proposals must also address the commitments of the Paris

Declaration on Aid Effectiveness and the Accra Agenda for Action, by including provisions to ensure transparency and accountability.^{21,22}

Prizes have been criticized for the complexity of the administrative structures required by their schemes.³ They necessitate the creation of numerous administrative groups to determine prize requirements, oversee the awarding of prizes, manage licences, and allocate funds.²³ Additionally, current proposals do not adequately address the potential for conflicts of interest among the individuals responsible for awarding prizes.²⁴ Nevertheless, prizes still appear to be operationally feasible because of their versatility – they have been used throughout history to induce innovation in fields ranging from aerodynamics to social entrepreneurship,²⁵ and can be implemented within the current pharmaceutical market.^{3,4}

One of the major challenges of operationalizing AMC revolves around the multiplicity of actors they involve. In addition to an independent adjudication committee, AMC also require a group coordinating manufacturer applications to participate in advanced markets, as well as another external organization to

manage funds.⁷ The complexity of this administrative structure contributes to the overall poor operational feasibility of this proposal. An additional challenge that arises relates to the accountability of the independent adjudication committee. Since some AMC proposals have suggested that the independent adjudication committee be formed by as few as five members,⁷ any conflicts of interest would have large ramifications.

The HIF does not appear operationally feasible. The HIF requires the formation of a governing structure with three branches (i.e., technical, assessment and auditing), a board of directors, and an administrative budget of up to \$600 million USD annually.⁸ In addition to this large expenditure, the ability of the assessment branch to effectively measure health impact is questionable.^{4,26} Assuming the suggested Quality-Adjusted-Life-Year (QALY) scale is able to accurately measure health, the HIF still faces the challenge of being unable to draw causal relationships between improvements in QALYs and the use of a particular pharmaceutical agent.²⁶ Health assessment is further complicated by the data collection process, which relies on often-inaccurate information from developing country sources.²⁶ This would potentially lead to unfair distribution of funds.²⁶ The HIF, however, attempts to improve accountability by including an auditing branch that oversees the assessment process.

Political Feasibility

To be considered politically feasible, proposals must be acceptable to the major stakeholders upon whose participation they depend.²⁷ Thus, political feasibility rests on developer and donor participation. Intellectual property (IP) needs to be given due consideration because, by ensuring that developers can exploit the benefits of their innovations, IP increases the likelihood of developer participation.²⁸

Prizes do not fare well on political feasibility. First, drug developers are disinclined to participate in these schemes because of their winner-takes-all quality – only a limited number of prizes are

awarded, and developers run the risk of creating a product for a competition but not receiving the reward.²⁹ Second, since prizes require developers to forfeit their IP upon receiving a reward,⁴ developers may be unwilling to participate in prize schemes. Donors are disinclined towards prizes because of the potential they raise for overpayment.³ Prizes are set prior to R&D and, as such, can only be based on estimates of the R&D costs.³ As well, because milestone-type prizes reward innovation before products have reached fruition, donors run the risk of awarding prizes for avenues of research that never reach the market.^{3,4}

From a political feasibility perspective, AMCs appear to fare well. Since donors are only required to pay for finished products, there is an added degree of certainty to their contributions.⁷ One drawback to AMCs, however, is that in early-stage development, the costs, risks and potential returns of R&D investments cannot be accurately estimated,¹⁸ potentially leading to terms that over- or under-pay developers. In spite of this, in 2009 the governments of Canada, Italy, Norway, Russia and the United Kingdom, along with the Gates Foundation, committed to participate in the AMC for a pneumococcal vaccine.¹⁹ This suggests willingness on the part of major donors to contribute to AMCs, and the accomplishments of this initial pilot could further encourage donor support. Furthermore, IP considerations make AMCs attractive from a developer perspective. In contrast to prizes, AMCs allow developers to retain the IP over their products. By reducing the cost of drugs in developing countries, AMCs reduce the incentive to counterfeit drugs and infringe on patents, as well as the need for compulsory licensing.³⁰ This, in effect, actually strengthens IP, making this proposal attractive to developers, and therefore more politically feasible.

The HIF strengthens IP in a similar fashion to AMCs – reducing drug prices while retaining IP.⁸ The biggest political challenge for the HIF, however, is in convincing developers to invest money into R&D for neglected diseases. Given the costs of R&D, firms need to be confident that their remuneration



mechanism – health impact – has proven reliability. Pay-for-performance schemes have been successfully implemented in the past (e.g., Quality and Outcomes Framework in the United Kingdom), but none have been directly analogous to the mechanism proposed by the HIF.²⁵ Thus, performing a pilot study that uses health impact as reward mechanism might promote developer participation. Developers, who would stand to increase their revenue through the HIF, could then use their strong lobbying powers to pressure governments into acting as donors for the HIF.²⁶ For donors, the pay-for-performance mechanism is attractive, but the \$6 billion USD annually required to fund the HIF would serve as a deterrent.

Financial Feasibility

For proposals to be financially feasible, they need to take into consideration the current economic climate. In recent years, major financiers of global health initiatives, like the United States, have faced trying economic conditions, which have reduced their willingness to provide aid for global health issues;³¹ consequently, proposals that place a low financial burden on donors would be preferable. Incentivizing mechanisms for R&D require a large operating budget, and in their current forms none of the proposals include self-sustaining funding mechanisms. Instead, they rely solely on an ongoing supply of donor funding. The pilot AMC for the pneumococcal vaccine cost \$1.5 billion USD for a late-stage product,¹⁶ and development of early-stage products are predicted to cost \$3 billion USD.⁷ The HIF requires a heftier operating budget of a minimum \$6 billion USD annually.⁸ Given that the Global Fund, a large and well established organization, has paused the offering of new grants until 2014 due to a lack of funding,³² it seems even less likely that establishing any of these proposals is possible.

Each proposal has been assessed on the basis of its operational, political and financial feasibility; the interplay of these three considerations determines a proposal's overall feasibility. Prizes appear to be the

easiest of these proposals to implement within the current pharmaceutical market, but seem unlikely to draw donor and developer support. Without the participation of these key players, prizes do not appear feasible. Although AMCs are more difficult to implement and require the creation of a new and extensive governance structure, past evidence suggests their appeal to major stakeholders is sufficient to overcome these operational challenges. Unlike prizes, AMCs are attractive to both donors and developers, therefore they seem feasible. For the HIF, the operational objection over the use of health impact to determine pay-for-performance may make it unattractive to developers. This concern must be addressed for the HIF to become a feasible way of promoting access to medicines. It is important to note, however, that each of the three proposals assessed here all lack reliable donor money. To address this concern, these proposals should be coupled with self-sustaining financing mechanisms.

Impact in Low- and Middle-Income Countries

The impact of a proposal on health in developing countries depends on its ability to produce affordable drugs that are effectively distributed. One of the significant barriers in access to medicines is price.³³ Since up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, family illness requiring medications is a major cause of household impoverishment.^{34,35} Since even the smallest additions to drug costs can serve as a deterrent to patients in developing countries, and retail markups and taxes contribute up to 80% of consumer prices,³⁶ proposals should also address costs to consumers. Moreover, the WHO estimates that 50% of all medicines worldwide are either prescribed, dispensed or sold inappropriately,³⁷ highlighting the need for proposals to also address the effective distribution of medications.



A pharmacist in an International Medical Corps mobile health clinic dispenses medicine to a sick child in a remote village in Pakistan's Sindh province. DFID, Vicki Francis, 2010.



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Prizes require that developers relinquish their IP rights in exchange for rewards, allowing for generic manufacture.^{3,4} While this provision is meant to make essential medicines more affordable for developing countries, inefficient procurement and distribution of generic products mean that public sources often are unable to meet demand.³⁸ Consequently, patients are often forced to purchase generic drugs from private retailers who charge two to three times more than their public counterparts.³⁸ Since prizes fail to address drug distribution, they are not comprehensive in ensuring access to medicines.

AMCs reduce drug prices for developing countries through donor subsidies, where donors pay the majority of the cost of a drug and developing countries pay part of the cost.⁷ While this is intended to increase affordability, in the case of the 2009 pneumococcal vaccine, the co-pay for developing countries was criticized for not being low enough.¹⁸ Additionally, like prizes, AMCs do not incentivize effective distribution of medications.⁷

Upon registering with the HIF, developers are required to sell their products at cost, receiving

payouts proportional to their product's health impact.⁸ This reward mechanism creates incentives for pharmaceutical developers to pursue activities that maximize the health impact of their products. Developers would have strong incentives to lobby retailers and governments to keep prices low.⁸ Currently, firms dedicate large sums of money to advertisement;³⁹ under the HIF, however, developers stand to benefit more from promoting proper distribution and use of their products.⁸ For example, developers would want to educate physicians on the proper use of their products, as this would directly affect profits.⁸ The HIF is therefore unique in comparison to the other proposals because it not only addresses low drug costs, but also ensures effective drug distribution to the target population.⁸

While all the proposals attempt to address the current paucity of drugs targeting neglected diseases, the HIF is the only proposal that considers how distribution, retail markups and taxes contribute to the inaccessibility of medicines. Of the proposals discussed here, the HIF would seem most able to improve health in low- and middle-income countries.

Health worker injecting vaccine to a child. Legazpi City, Albay, Philippines. Project WHSMP2. World Bank, Kenneth Pornillos, 2011.



Conclusions

Of the three proposals, the HIF would seem to be the most effective at improving health in developing countries; however, it appears neither operationally nor politically feasible at this time. Should issues with the health impact measurement be resolved, and the economic climate become more favourable in the future, the HIF could effectively address access to medicines around the world.

The obstacles posed by the poor political feasibility of prizes seem to suggest that this proposal is not appropriate for the development of new drugs. Despite this limitation, if used to promote research that is less cost-intensive as has been done in the past, prizes could still have a place in efforts to improve health in developing countries.

As long as the co-pay and tail prices are kept sufficiently low, AMCs could be used to produce new and affordable drugs for the global poor. Though AMCs are not as comprehensive as the HIF in addressing all of the barriers in access to medicines, they appear to be much more feasible. Evidence from the pilot AMC for the pneumococcal vaccine indicates that where there are willing donors and willing developers, operational challenges can be overcome.¹⁶ AMCs should work in conjunction with research grants to reduce the risk of early-stage R&D. Additionally, should AMCs survive in the long term, they will need to work in synergy with a self-sustaining funding mechanism and rely less on donor money.

Actionable Key Messages

- ⇒ To promote access to essential medicines, proposals must address the risk associated with early-stage R&D for neglected diseases.
- ⇒ In the current economic climate, proposals should work in synergy with self-sufficient financing mechanisms, so that they rely less heavily on donor funds.
- ⇒ Coupled with research grants and sustainable funding, AMCs should be implemented, as they provide a feasible way to create new and affordable drugs for the global poor.

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Nuth Tith, 54, a Cambodian drug inspector, checks for illegal or fake drugs at a pharmacy near the Thai-Cambodian border. The Gates Foundation, 2011.

Chapter 5

Biomedical R&D Treaty, Removal of Data Exclusivity and Transferable Intellectual Property Rights

Daniel Glatt, Jillian Horning and Karen So

Introduction

The pharmaceutical industry has been responsible for most drug and vaccine innovations in the modern era, but the current model of pharmaceutical development is no longer sustainable due to rising costs.¹ This is combined with new global expectations that pharmaceutical companies develop medicines for neglected diseases (NDs), developing countries be given greater influence over global pharmaceutical policy, and the costs of research and development (R&D) be disassociated from the costs of the final product.²

This chapter assesses three proposals for global access to medicine reform: 1) a Biomedical R&D Treaty; 2) removal of data exclusivity; and 3) transferable intellectual property rights. Each proposal was evaluated for its potential public health impact in developing countries; cost-effectiveness and financial feasibility; intellectual property management issues; and potential political support. Benefits of implementing the three proposals together was also considered.³

Overview of Proposals

The R&D Treaty

The R&D Treaty would be an international, legally binding agreement between nations or pharmaceutical companies that aims to improve the financing and coordination of R&D globally. Four aspects for a R&D Treaty have been identified by stakeholders: 1) ensuring sustainable investment in medical innovation; 2) providing fair allocation of cost burdens of innovation; 3) creating mechanisms to drive R&D investment into areas of greatest need; and 4) providing the flexibility to utilize diverse and innovative methods of financing pharmaceuticals while ensuring access and protection for consumers.^{2,4,5} The proposed R&D Treaty supports global health governance by creating a framework that other initiatives can be built around.⁴ It would also establish global norms to promote sustainable financing for R&D and management of intellectual property (IP).^{2,5}

Abstract

This paper analyzes three proposals for improving access to essential medicines for neglected diseases: the Biomedical R&D Treaty, removal of data exclusivity, and transferable intellectual property rights. Each proposal was evaluated for its potential health impact in developing countries; cost-effectiveness and financial feasibility; intellectual property management issues; and potential political support. It was determined that in their current forms, the Biomedical R&D Treaty and removal of data exclusivity could not be successfully adopted. Transferable intellectual property rights would need to be adopted in conjunction with a long-term solution to improve its political attractiveness.

Removal of Data Exclusivity

Data exclusivity was designed to act as protection against “unjust competition” in the pharmaceutical market.⁶ This proposal calls for the removal of data exclusivity to increase the production of pharmaceuticals. Before data exclusivity was incorporated into policy and agreements, generic pharmaceutical companies were permitted to use innovators’ clinical trials data when submitting products for market approval.⁷ The generic drug companies’ products have the same safety as innovators because they are chemically identical to the brand-name product.⁷ However, with data exclusivity, generics can no longer use innovators’ data for a set period of time, typically five to 10 years.^{6,8} Removing this provision allows generics to gain earlier approval from regulatory bodies and make advance preparations for distribution so that medicines can be made available at cheaper generic prices immediately upon expiry of relevant patents.

Transferable Intellectual Property Rights

Transferable IP rights aim to address the lack of development and investment towards pharmaceuticals for neglected diseases. This proposal would allow a company to receive a patent extension on a drug of their choice in exchange for developing a drug or vaccine for a neglected disease.^{1,9} The goal of the proposal for transferable IP rights is to greatly reward high impact, complex and innovative solutions; low impact or easy discoveries would receive smaller patent extensions, thus encouraging companies to work on difficult issues.¹⁰

Potential Public Health Impact in Developing Countries

The ideal end-goal for all proposals for access to medicine reform is to create a positive public health impact in developing countries. This goal could



be accomplished in the short term by increasing development or availability of pharmaceuticals geared towards neglected diseases; and in the long term by increasing capacity for production and R&D of pharmaceuticals in developing countries. Overall, these changes would increase the developing world’s role in innovation, governance and decision-making.

The R&D Treaty

The R&D Treaty proposes to incorporate mechanisms to improve research and innovation, particularly in developing countries. This could be accomplished through the creation of collaborative projects that expand developing countries’ capacity and their R&D-based pharmaceutical and biotech industries, which was accomplished in South Korea during the 1990s.¹ The R&D Treaty aims to create a greater partnership among companies, national governments and international organizations in finding effective ways to harness their expertise so



as to develop new treatments and cures for diseases that primarily affect the poor.^{7,11} A requirement of the proposed R&D Treaty is that products must be more effective than what is currently available on the market, in order to receive funding.^{2,12-15} This ensures that new pharmaceuticals will have a real impact in developing countries.

Removal of Data Exclusivity

Removing data exclusivity allows companies in developing countries to increase production and availability of pharmaceuticals in a shorter timeframe.¹⁶ After data exclusivity lapses it still takes one to three years for generics to be registered and permitted to enter the market.¹⁶ Removing data exclusivity would also allow national governments to increase their role in decision-making by deciding how pharmaceuticals will enter their markets, and actively choosing vendors for pharmaceuticals.¹⁷ Without data exclusivity, governments could provide

funding to local generic pharmaceutical companies to manufacture and distribute necessary medicines, rather than importing them for longer periods from outside countries – increasing availability and affordability.¹⁸

Transferable Intellectual Property Rights

The transferable IP rights proposal clearly aims to impact health in developing countries, but the way this will be achieved is not certain. Specifically, the proposal document acknowledges that clear criteria must be established to determine the length of a patent extension for an existing pharmaceutical, which is based on a drug's ability to treat neglected diseases.¹⁰ However, the proposal provides little guidance on how each patent extension term would be defined or how transferable intellectual property rights would be implemented globally. Another issue is that this model only rewards development of pharmaceuticals while doing little to increase their delivery.¹⁰ The proposal document states that if innovative companies do not produce the pharmaceutical themselves, they must facilitate its production by providing a free licence to a third party.¹⁰ Another weakness of this proposal is that it does not address the long-term goal of increasing capacity for R&D, as well as for innovation, governance and decision-making in developing countries.

The main strength of transferable intellectual property rights is that it could be very effective in meeting the short-term goal of increasing availability and development of pharmaceuticals targeting neglected diseases, especially since this proposal provides strong financial incentives, IP management and political motivations. If guidelines are clearly defined prior to adoption, this proposal could perhaps be implemented relatively easily – in part because of its ability to have rapid health impacts.¹ Further, this proposal creates advantages for small biotechnology firms, which have innovative ideas but lack capital, and cannot proceed with trials.^{1,10} The



transferable intellectual property rights model would encourage innovative pharmaceutical companies to purchase the research of smaller firms and conduct multi-phase trials to reap the benefits of patent extension.¹⁰ If innovators do not purchase this research and conduct trials, then it is likely to remain in the laboratory phase resulting in no benefit to public health.

Cost-Effectiveness and Financial Feasibility

In order for proposals to be accepted by governments and the pharmaceutical industry, they must be more cost-effective than the status quo. Proposals are cost-effective if they reduce the cost of R&D for companies, lower product costs for purchasers (e.g., governments, insurers, patients), and/or save money by improving distribution networks. Financially feasible proposals increase available funds for R&D, maintain profits, are affordable to national governments, or create greater cost-effectiveness for purchasers.

The R&D Treaty

National government involvement is important for the R&D Treaty as they would bear the responsibility for its initial development costs.^{7,11} The R&D Treaty would give governments the normative powers to direct financing of R&D through two different mechanisms: direct funding and the prize/grant model.^{2,12-15} Direct funding would be granted to academic institutions or specific companies to carry out R&D projects.² In the prize model, countries would pool money into funds which would be allocated each year to different companies based on the impact of their product(s).^{2,12-15} Direct funding and prizes can also be provided by large philanthropic organizations like the Gates Foundation.^{2,4} By having greater control of funding, governments can ensure that money is funnelled into high impact initiatives.

The R&D Treaty calls for horizontal funding to give developing countries the flexibility to focus on diseases according to their own needs and priorities.¹⁹

The proposal also shifts the monetary responsibility and risks away from companies and onto national governments, thereby making R&D a global public good.^{2,5,13-15} By making pharmaceuticals a public good, governments would be able to regulate and de-link prices from the cost of R&D and manufacturing. Further, with the help of donor nations and foundations, developing countries can conduct their own research.¹

There are also concerns that this proposal will ultimately not be cost-effective. While it could result in cost savings for national governments (since they would pay lower pharmaceutical prices),² it may not be cost-effective in the short term as it requires upfront funding, which is highly unattractive in the current international financial climate.

It has been proposed that the R&D Treaty could be financially feasible if many countries, particularly the most wealthy, dedicate 1% of their Gross Domestic Product (GDP) towards R&D financing.^{2,15} However, in many developing countries, such investment towards R&D may not be financially feasible,² and greater contributions from developed countries are unlikely to attract much political support.^{2,15} One percent of GDP from most countries is necessary to de-link the cost of R&D from product prices, yet such support is unlikely to achieve widespread buy-in. Due to uncertainty regarding how funding will be secured and whether the new system would be cost-effective, this proposal, as of now, seems financially infeasible.

Removal of Data Exclusivity

One goal of data exclusivity is to extend the time in which innovative pharmaceutical companies have a monopoly over the sale of the products they develop, allowing the innovator to charge relatively high prices and recover R&D costs.²⁰ Data exclusivity also exists to protect innovators against unfair commercial use of their data, particularly when patents do not exist or are ineffective due to administrative delays.¹¹ When patents exist, data exclusivity prevents generics from producing generic drugs in anticipation of market entry prior to patent expiry.²¹ Removing data

exclusivity would decrease revenues for innovators and could have negative effects on innovation by weakening their ability to recover the costs of R&D.¹

Creating an international ban on the inclusion of data exclusivity into future policies and agreements would have low costs to governments.⁸ This would be beneficial for generics as they would be able to use innovators' clinical trial data earlier in their regulatory filings.²² Removing data exclusivity creates more market competition by increasing the number and amount of drugs in the market, resulting in lower prices for consumers.^{8,22}

Removing data exclusivity would be cost-effective for governments and citizens, but would decrease profits for innovators. Unless another compensative mechanism was introduced, such as stronger patent laws or direct funding of R&D, the development of new drugs could be affected.⁶

Transferable Intellectual Property Rights

The transferable IP rights proposal would require little external capital to be adopted, but needs international agreement on a patent extension model. This would likely be accomplished through the World Trade Organization or World Intellectual Property Organisation.²³ Transferable IP rights would encourage R&D of pharmaceuticals for neglected diseases, as the extension can be applied to a product with a proven record of revenue generation.¹⁰ For example, Pfizer's U.S. patent on Lipitor – a drug that treats high cholesterol – expired in November 2011.²⁴ Had transferable IP rights existed, Pfizer could have extended this profitable drug patent by developing a needed product in the neglected market. Additionally, under this proposal, costs of R&D do not need to be recouped through the sale of the final product, allowing the price of the drugs for neglected diseases to be set at or below costs — making them affordable to those most in need.

However, in the long term, this proposal would be very expensive for both developed and developing





countries. The drugs most likely to have their patents extended are expensive blockbuster drugs. By delaying the entry of generics, the cost per unit of the brand-name drug will remain higher due to this monopoly.²⁵ The impact of having novel drug options for most neglected diseases would be outweighed by the benefits of having cheaper generics to combat chronic diseases.²⁶ Cardiovascular diseases are the largest contributor to the global burden of disease in terms of global deaths and disability (29.3% and 10.7% respectively).^{1,26} The availability of cheap generic Lipitor, for example, would have a greater impact on public health in developing countries than drugs targeting all tropical diseases.²⁶ Additionally, transferable IP rights would create uncertainty regarding when generics would be available and who ultimately pays the costs of developing new pharmaceuticals that target neglected diseases. This proposal would delay access to generic drugs, raise average drug prices, and increase insurance premiums and tax burdens in all markets.⁹ Rising pharmaceutical costs would reduce revenues for generic drug companies and create uncertainty for national drug budgets.⁹

Intellectual Property Management Issues

To be successfully implemented, a proposal must be coherent with IP norms. The goal of IP is to protect innovation, the innovative process and the innovator.¹ For research-based pharmaceutical

companies, this is currently accomplished through patents and data exclusivity.²⁷ Currently, there is opposition from these companies to introduce changes that would weaken the IP protections from which they currently benefit, which must also be considered.

The R&D Treaty

The R&D Treaty could weaken IP management overall by creating an alternative system to patents that has free dissemination of information – including knowledge, materials and technology.^{2,7,11,14,15} This alternative system could be strengthened by increasing the quantity of research funding or by creating an international research funding body, whose focus would be to develop pharmaceuticals for neglected diseases.² This would be necessary because current public capacity cannot supplant companies in terms of innovation, quality of R&D and distribution.^{2,15} The R&D Treaty is unlikely to succeed because it is less attractive than the status quo for many companies and goes against the norms of strengthening IP laws.

Removal of Data Exclusivity

One argument for removing data exclusivity is that it is being misused to extend pharmaceutical companies' monopolies past the patent term on their products.²² The removal of data exclusivity in relation to IP is structurally viable. It could be easily enforced by adopting an international agreement banning data



Residents near Savelugu Town, Ghana, travelling to a further water supply to avoid guinea worm disease. Gates Foundation, 2008.

exclusivity periods in signatory countries. Further, signatories could agree not to introduce or re-adopt data exclusivity practices in their jurisdictions. Developing countries would likely be in favour of its removal, since many of them were pressured to adopt data exclusivity against their interest by the U.S., European Union and Japan.^{8,17,27}

However, the removal of data exclusivity would be a reversal to the global trend of strengthening IP law. This proposal would not be supported by the most powerful drug companies or countries that have greater control and decision-making influence in the pharmaceutical industry. The proposal does not provide any benefit to these entities, making it unlikely to be adopted in the present international climate.

Transferable Intellectual Property Rights

Innovative pharmaceutical companies support transferable IP rights because it works within the existing IP system and extends their monopoly on their “drug of choice”.^{1,10} With clear guidelines, a corporation would be able to determine if a transfer of IP rights could offset the costs of R&D for a neglected medicine. Currently, many blockbuster drugs have, or are going to, reach the end of their patent lives with few or no clear candidates to replace their revenue streams.²⁸ This creates an opportune environment for the adoption of this proposal and could rapidly result in drugs for neglected diseases, since innovators could use transferred rights to maintain revenue streams.

Political Support

Proposals must be desirable for powerful stakeholders to receive support. These stakeholders include governments, companies and major philanthropic organizations. Proposals that are politically difficult to adopt or create management issues necessarily reduce political feasibility. Proposals that are attractive to most or all key stakeholders and that are easily implemented are more politically feasible.

The R&D Treaty

While there is potential for an R&D Treaty, it is currently too vague, unfocused and underdeveloped to be successfully implemented. There is some agreement in the overarching goals of the R&D Treaty, however, existing proposals fail to reach consensus regarding the implementation of these principles.

To be more attractive, advocates of the proposed R&D Treaty must change the perception of the actors managing innovation and development of medicines. The R&D Treaty calls for a re-balancing of decision-making processes, increasing the role of national governments – particularly those of developing countries – and decreasing the influence of companies.^{2,12,14,15} For this to be accomplished, all national governments must increase funding for R&D, giving them greater control over resulting patents. This would be difficult as developing countries do not necessarily have the capital to invest in R&D.^{2,29} Further, there are few incentives in the proposal for developed countries to assume additional costs.^{2,29} Innovators also have few incentives to reduce their monopoly on innovation and adopt alternative mechanisms, including information and profit sharing.^{12,15,19}

Smaller pharmaceutical companies and developing countries would clearly benefit from the R&D Treaty.^{7,11,19} However, these groups do not necessarily have the required level of influence to support this proposal.^{7,11,19} The R&D Treaty would require a degree of international cooperation and solidarity that would be unprecedented. Since the R&D Treaty cannot gain support from most key stakeholders, it is likely politically infeasible.

Removal of Data Exclusivity

While the removal of data exclusivity is structurally feasible to institute through policy, politically this concept would not be accepted in its current iteration. The removal of data exclusivity would negatively impact the profits of innovative



pharmaceutical companies.⁶ The proposal does not provide them any incentives, such as alternative funding mechanisms to recoup R&D costs. Since these companies are necessary for innovation, any changes of international drug policies need their support.¹ As such, the removal of data exclusivity is politically infeasible.

Transferable Intellectual Property Rights

The level of support for the introduction of transferable IP rights from national governments is uncertain. Creating an effective system to support this proposal that would “incentivize high-innovation products in priority health areas – the desired goal – is likely to be so complex [that it would be] unworkable for stakeholders”.¹⁰ Further, this proposal is likely to fail due to the international recession and its effects on national health budgets. Already, so much of national health budgets are allocated towards pharmaceuticals;³⁰ if generics were delayed entry to the market, government spending would only increase in those countries where governments subsidize their purchase

Despite its unattractiveness to governments, innovators find this proposal to be very attractive as it would increase patent-life and could easily increase profits. Companies could potentially place enough pressure on countries to adopt this proposal as policy if they were willing to make other concessions, such as better post-market surveillance on the long-term effects of pharmaceuticals.

Conclusion

In summary, the R&D Treaty is currently too vague, unfocused and underdeveloped to be successfully implemented. The removal of data exclusivity will not be supported by innovative pharmaceutical companies without a supplementary funding mechanism. Of the three proposals assessed in this chapter, only the transferable IP rights proposal has a realistic chance of being adopted as a short-term

Actionable Key Messages

⇒ Proposals for a Biomedical R&D Treaty, removal of data exclusivity and transferable intellectual property rights could have positive impacts on the development and availability of essential medicines in developing countries.

⇒ All three proposals require refinement prior to any form of implementation – but the Biomedical R&D Treaty and the removal of data exclusivity are not recommended.

⇒ Transferable intellectual property rights could be beneficial as a short-term option if combined with a better long-term solution.

pharmaceutical strategy, and could offer some benefit if implemented in conjunction with a longer-term option like the Health Impact Fund. This is necessary since transferable IP rights would be expensive to maintain over a long period of time. Under their current iterations, it is inadvisable that any of these proposals be adopted as they all require major revisions.

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Sign of a community health clinic in Ghana. Abraam Salama, 2010.



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