

UNITED NATIONS SECRETARY-GENERAL'S
**HIGH-LEVEL
PANEL ON ACCESS
TO MEDICINES**



BACKGROUND PAPER:

Existing and prior work, initiatives and
proposals to improve innovation and access to
health technologies

Prepared by Brook Baker, with the High-Level Panel Secretariat at UNDP
in collaboration with UNAIDS

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Introduction

The United Nations Secretary-General's High Level Panel on Access to Medicines ('the Panel') is not the first body that has been established to address the innovation of, and access to, health technologies. The global record is replete with initiatives of both large and small scale. Some of these initiatives have aimed, as the High-Level Panel will, at strengthening the coherence of relevant laws and policies which underpin health technologies innovation and access, while other initiatives have attempted to address discreet gaps which emerge in either innovation or access – or both – for specific types of technologies or disease, or particular demographic groups of end-users.

During its first meeting on 11-12 December 2015 in New York, the High-Level Panel expressed its commitment to taking cognizance of evidence around existing and novel approaches, wishing to acknowledge the significant efforts, successes and lessons-learned of those who have come before, and in order to avoid any unnecessary duplication. The purpose of this background paper is to provide Panel members with an overview of some such work and proposals, highlighting activities aimed at both policy reform to the common models that drive innovation and access, as well as activities aimed at filling specific gaps.

This brief summary does not do justice to the rich set of ideas about rebalancing trade/intellectual property (IP), human rights, and public health put forth by leading initiatives over the past 20 years, and this document is by no means comprehensive. However it does provide an overview and snapshot that will hopefully help contextualize the objectives and work of the High-Level Panel. The paper is divided into two major sections: Section A describes the work, declarations, recommendations, and outcomes of major initiatives to date at the global, regional or national levels, which have had objectives similar or related to those of the High-Level Panel, while Section B presents a brief literature review of models and ideas already underway, or that have been proposed in various forums to improve access to and innovation of essential health technologies. Section B draws in substantial part on a recently compiled mapping of such models – a forthcoming publication by Universities Allied for Essential Medicines, as well as other sources.

Part A. Previous initiatives, recommendations, and outcomes from major organizations and initiatives seeking new norms on innovation and access to health technologies

Part A of the paper reviews prior initiatives, declarations, outcomes, and recommendations of major multilateral organizations, concerning new approaches to incentivizing innovation of needed technologies, and ensuring access to resulting products. It reviews in some depth the work surrounding the World Health Organization's Global Strategy and Plan of Action on Public Health, Innovation, and Access to Medicines – widely considered the most significant effort to date. It also reviews clarifications and reforms at the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), particularly its adoption of a Development Agenda. While WHO, WIPO and WTO are preparing separate, more in-depth dossiers on their individual and collective agendas, the work of these agencies is still summarized here to provide a more complete overview of some of the major initiatives to date. Section A also reports on some of the most important normative statements – resolutions, declarations, and outcome documents which have emerged from the UN system and its bodies, including from the UN General Assembly, the World Health Organization, the Human Rights Council, the High Level Meetings on HIV and Non-Communicable Diseases (NCDs), and Special Rapporteurs both on the Right to Health and in the Field of Culture. Finally, Section A reports on other important yet non-binding initiatives, such as the UK Government's Commission on Integrating Intellectual Property Rights and Development Policy, the Global Commission of HIV and the Law, the London Declaration, the Washington Declaration on IP and the Public Interest, and the Max Planck Society Declaration on Patent Protection: Regulatory Sovereignty under TRIPS (TRIPS being the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights).

i. UN and other Multilateral Initiatives, recommendations, and outcomes

World Health Organization (WHO) Initiatives

As early as 1996, the WHO first began formally raising concerns about the link between IP and access to medicines, through a resolution of the World Health Assembly (WHA), which requested WHO to report on the impact of the WTO's trade rules with respect to national drug and essential medicines policies.¹ In 1998, that report, "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement"² was submitted. Subsequently in 2000, the [WHO Commission on Macroeconomics and Health](#) (CMH) was established, which took the view that patent protection offered little incentive for research on developing country diseases, in the absence of a significant market.³ As regards to access to medicines, the CMH favored establishing a system of differential pricing for developing countries and more extensive use of compulsory licensing where necessary.⁴ The CMH recommended an

additional \$3 billion be spent annual on R&D through a new Global Health Research Fund, existing mechanisms, and public-private partnerships.⁵

The [Commission on Intellectual Property Rights, Innovation and Public Health](#) was later created in May 2003 at the Fifty-sixth WHA pursuant to resolution WHA56.27. The resolution requested that WHO establish terms of reference for a body to collect data and proposals from various stakeholders and produce an analysis of IP rights, innovation, and public health, including the question of an appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries, and to submit a progress report to the Fifty-seventh WHA, and a final report with concrete proposals to the Executive Board at its 116th session.⁶ The Commission published its report in 2006 and made a total of 60 recommendations.⁷ The Report summarized the key issues involved in promoting sustainable governmental financing of research as follows:

- "Identification of gaps in the current coverage of research for diseases that disproportionately affect developing countries.
- Actions that might contribute to increasing the overall R&D effort on diseases that predominantly affects the developing world, and improved priority setting. For example, recognizing the possible need for increased support for those that currently receive less attention than HIV/AIDS, TB and malaria.
- Providing a sustainable source of funding for public-private partnerships and other R&D institutions in the field.
- Seeking ways to channel greater funding to research organizations in developing countries in both the public and private sectors.
- Whether common interests of product developers and producers in various areas might be better addressed collectively in areas such as facilitating clinical trials and product delivery.
- Supporting product introduction in developing countries through improved regulation, at national, regional and international level.
- Monitoring the impact of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration on the TRIPS agreement and public health.
- Measuring performance and progress towards objectives, and monitoring and evaluation of programmes."⁸



The Report also identified several steps that might be taken with respect to IPRs:

- Countries and public research institutions and universities should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies.
- Developing countries need to consider adoption of research exemptions that might foster health-related research and innovation.
- Countries should provide for TRIPS-compliant compulsory licensing to promote research relevant to health problems in developing countries and to provide access to needed health commodities as well.
- Companies should adopt patent and enforcement policies facilitating greater access to needed medicines in developing countries.
- Parallel importation should be avoided in developed countries but retained in developing countries.
- Developing countries should adopt only limited forms of data protection and should allow early working.
- The Doha Declaration should be respected in trade negotiations and any health trade-off should be carefully considered; bilateral trade agreements should not seek TRIPS-plus protections that might reduce access to medicines in developing countries.
- Developing countries should adopt and use competition policies remedy anti-competitive practices related to the use of medicinal patents.
- Governments should promote generic competition by adopting patentability criteria and patenting guidelines for patent examiners.⁹

Following up on the Commission's Report and seeking to foster innovation and improve access for people in developing countries, the WHA adopted in May 2008 resolution WHA61.21, and resolution WHA62.16, on a [Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property](#).¹⁰ The key elements of the Global Strategy, which were designed to promote innovation, build capacity, improve access and mobilize resources, were:

- prioritizing research and development needs,
- promoting research and development,
- building and improving innovative capacity,
- transfer of technology,
- application and management of intellectual property to contribute to innovation and promote public health,
- improving delivery and access,

- promoting sustainable financing mechanisms, and
- establishing and monitoring reporting systems.

The Global Strategy was first operationalized in 2008, when the World Health Assembly resolution established the Expert Working Group (EWG) to take the Global Strategy forward. Among concerns of inappropriate industry influence however, the report of the EWG was not accepted by Member States, and the [Consultative Expert Work Group on R&D: Financing and Coordination](#) (CEWG) was subsequently established in 2010.¹¹ The CEWG issued a report in 2012, after which the WHO Director-General was requested to facilitate the implementation of a few [health R&D demonstration projects](#). In November of 2013, WHO regional offices shortlisted 22 projects for consideration by CEWG and other experts who thereafter identified 7+1 proposals with potential to be demonstration projects. Following solicitation and receipt of further information and stakeholder meetings, indicators to measure success were identified and finally in March of 2014 four projects were identified as ready for implementation:

- The Visceral Leishmaniasis (VL) Global R&D & Access Initiative – Drugs for Neglected Diseases initiative (proponent: Drugs for Neglected Diseases Initiative);
- Exploiting the pathogen box: an international open-source collaboration to accelerate drug developing in addressing disease of poverty (proponent: Medicines for Malaria Venture);
- Development of Class D Cpg Odn (D35) as an Adjunct to Chemotherapy for Cutaneous Leishmaniasis and Post Kala-Azar Dermal Leishmaniasis (Pkdl) – United States Food and Drug Administration (proponent: US FDA, et al.);
- Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases - African Network for Drugs and Diagnostics Innovation (proponent: African Network for Drugs and Diagnostics Innovation, et al.).

The two Leishmaniasis proposals have since been consolidated, and one of the other four most promising proposals has been withdrawn. Further stakeholder meetings have been held on each of the selected demonstration projects. The three promising proposals not yet accepted are being further developed.¹² It is worth noting that the WHO has also undertaken a trilateral analysis on IP, innovation and access to medicines with the WTO and WIPO¹³ (further detail of which will be found in forthcoming dossiers being prepared by those organisations for Panel members).

While the objectives of the WHO's work are closely related to those of the High-Level Panel, it should be noted that the mandate of the High-Level Panel is broader, encompassing all technologies for all diseases and in all countries, regardless of income or level of development. The CEWG, furthermore, accepted existing trade laws (notably the TRIPS Agreement) as the established global norm and did not

seek or discuss proposals that may seek to alter this legal situation. In this way, while reactions to the CEWG were broadly welcoming, concerns were raised by some that more novel and risky ideas (that would have delinked the cost of drug R&D from prices) were rejected in favor of the eight shortlisted proposals, which were more immediately viable as they build on existing efforts and focused on specific diseases.¹⁴ The WHO is conducting a comprehensive evaluation and overall programme review of the Global Strategy – the WHO Executive Board issued a short report in December 2015, providing an update on establishment of a global health research and development observatory, an update on implementation of demonstration projects, as well as an update of exploration of financing mechanisms for contributions to health research and development,¹⁵ with a final report due to be presented to the WHA through the Executive Board in 2018.

World Trade Organization (WTO) Initiatives

The TRIPS Agreement, which set global norms for IP rights and enforcement, including those impacting access to medical technologies, originated in and is overseen by the WTO. One of the key provisions of the TRIPS Agreement is Article 27.1, which set minimum standards of intellectual property protections for all Members, thereby reducing much of the policy space, or flexibility, that countries previously held to set and apply IP standards as deemed nationally appropriate, including excluding patents on pharmaceutical products. On four separate occasions the TRIPS Council or the General Council has taken steps that clarify or confirm flexibilities found in the TRIPS Agreement that impact public health. In 2001, following multiple actions by the US and others that had challenged low- and middle-income countries' right to adopt and utilize flexibilities set forth in the TRIPS Agreement, the Africa Group demanded a clarification of those flexibilities from the TRIPS Council. The result was the [Doha Declaration on TRIPS Agreement and Public Health](#), WT/MIN(01)/DEC/2,¹⁶ by which all WTO Members confirmed:

- “1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.*
- 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.*
- 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.*
- 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a*

*manner supportive of WTO members' right to protect public health and, in particular, to promote **access to medicines for all**.*

*In this connection, **we reaffirm the right of WTO members to use, to the full extent, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.***

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*
- b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*
- c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*
- d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."*

Paragraph 6 of the [Doha Declaration](#) addressed the particular problem of developing countries that lacked sufficient pharmaceutical manufacturing capacity to satisfy their need for more affordable medicines pursuant to a compulsory license:

"We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

Although Paragraph 6 of the Doha Declaration mandated an expeditious solution to this problem, it took just over 20 months to come up with a temporary waiver, the Decision of 30 August 2003,¹⁷ that permits countries to import specific quantities of needed pharmaceuticals and allows for other countries to supply those needs when required notices and compulsory licenses have been issued. The waiver has been proposed as an amendment in Article 31bis of the TRIPS Agreement, but it has not yet been ratified by a sufficient number of Member States. Given the onerous procedural requirements, and due to the fact that it has only been used once since adopted, there is considerable sentiment that

the Paragraph 6 System is not working and there have been calls for a major reconsideration of the waiver.¹⁸

[Paragraph 7 of the Doha Declaration](#) directly addressed LDC Members' need for an extended transition period with respect to pharmaceutical products:

“We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.”

Actualizing Paragraph 7's command, the TRIPS Council decided on 27 June 2002 that: “Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016.”¹⁹ This so-called pharmaceutical extension was further extended until 2033 on 6 November 2015.²⁰

Least-developed country (LDC) Members had been granted an initial 10-year exemption until 2006 from implementing any TRIPS obligations in Article 66.1 of the TRIPS Agreement. Following a duly motivated request submitted by LDCs as a group in October 2005, the TRIPS Council adopted decision IP/C/40, which gave LDCs an extension of 7.5 years that exempted LDCs from having to apply any TRIPS provisions, other than Articles 3, 4 and 5 until 1 July 2013.²¹ On June 11, 2013, the TRIPS Council further extended the general TRIPS-compliance transition period until 2021.²²

[World Intellectual Property Organization \(WIPO\) Initiatives](#)

At its General Assembly in 2007 and in response to requests from developing country members, WIPO Member States adopted 45 recommendations (out of the original 111 proposals), forming the organization's Development Agenda.²³ The proposals are organized into six clusters: technical assistance and capacity building; norm-setting, flexibilities, public policy and public domain; technology transfer, information and communication technologies and access to knowledge; assessment, evaluation, and impact studies; institutional matters including mandate and governance; and other issues. Of closer relevance to the High-Level Panel's mandate, the recommendations include:

- “13. WIPO’s legislative assistance shall be, inter alia, development-oriented and demand-driven, taking into account the priorities and the special needs of developing countries, especially LDCs, as well as the different levels of development of Member States and activities should include time frames for completion.*
- 14. Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement.*
- 17. In its activities, including norm-setting, WIPO should take into account the flexibilities in international intellectual property agreements, especially those which are of interest to developing countries and LDCs.*
- 22. WIPO’s norm-setting activities should be supportive of the development goals agreed within the United Nations system, including those contained in the Millennium Declaration. The WIPO Secretariat, without prejudice to the outcome of Member States considerations, should address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as: (a) safeguarding national implementation of intellectual property rules (b) links between intellectual property and competition (c) intellectual property -related transfer of technology (d) potential flexibilities, exceptions and limitations for Member States and (e) the possibility of additional special provisions for developing countries and LDCs.*
- 23. To consider how to better promote pro-competitive intellectual property licensing practices, particularly with a view to fostering creativity, innovation and the transfer and dissemination of technology to interested countries, in particular developing countries and LDCs.*
- 25. To explore intellectual property -related policies and initiatives necessary to promote the transfer and dissemination of technology, to the benefit of developing countries and to take appropriate measures to enable developing countries to fully understand and benefit from different provisions, pertaining to flexibilities provided for in international agreements, as appropriate.*
- 45. To approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to*



social and economic welfare, and to a balance of rights and obligations”, in accordance with Article 7 of the TRIPS Agreement.”

WIPO has undertaken specific activities on flexibilities in the intellectual property system, including within the patent system, and its Standing Committee on the Law of Patents has undertaken significant and useful work studying patent flexibilities both on a topical and regional level.²⁴ Nonetheless, a 2011 external review of WIPO’s early development work was relatively critical, finding shortcomings in the scale and inclusiveness of its development-related activities, making multiple recommendations for improved practice.²⁵

Recognizing the need for more progress in neglected tropical diseases (NTDs) research, WIPO Re:Search was formed in 2011 through the efforts of several of the world’s leading pharmaceutical companies and BIO Ventures for Global Health. WIPO Re:Search was founded on the belief that sharing intellectual property and know-how (compounds, compound libraries, unpublished findings, regulatory dossiers, screening and platform technologies, expert know, and where appropriate patent rights) could help drive innovation in the search for new products to treat NTDs, malaria, and tuberculosis. In terms of access, guiding principles state that products developed through Re:Search partnerships would be accessible royalty free in least-developed countries, and would be available for good faith access in all developing countries, taking into account their economic development and the need of disadvantaged populations. WIPO Re:Search now involves 111 different partners and has helped to broker 50 research agreements.²⁶ An updated independent review of the implementation of the Development Agenda Recommendations is currently underway.

Key United Nations Resolutions and Reports

The UN system has issued multiple proclamations that relate to implementation of TRIPS flexibilities and the importance of access to medicines for all. Also as requested by members of the High-Level Panel during its first meeting in December 2015, a separate background paper on international human rights law norms regarding access to medicines and the rights of inventors has been prepared by the Secretariat. That paper contains a more comprehensive analysis of the statements by key UN human rights bodies and its rapporteurs, but some bear mentioning in this overview paper as seminal statements.

At the UN’s highest level, the General Assembly has passed several resolutions (which are formal expressions of the opinion or will of UN organs) in this context. Most recently, in unanimously adopting Sustainable Development Goal, Target 3.b. relating to health for all, UN Member States highlighted the

relevance of IP on access to medicines while simultaneously affirming the goal of universal access to pharmaceutical products, which included the following target:

“Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.”²⁷

A previous resolution, adopted on 16 September 2013, contains language repeating previous urgings, stressing the need to promote access to medicines for all and to encourage the provision of assistance to developing countries in this respect. It reads:

“23. Reaffirms the right to use, to the fullest extent, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health, the decision of the General Council of the World Trade Organization of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and, when formal acceptance procedures are completed, the amendment to article 31 of the Agreement, which provide flexibilities for the protection of public health, and in particular to promote access to medicines for all...”²⁸

A 12 December 2012 resolution similarly recognizes that fulfilment of basic health services – including medicines – should not cause financial hardship. It states that:

“10. Acknowledges that universal health coverage implies that all people have access, without discrimination, to nationally determined sets of the promotive, preventive, curative and rehabilitative basic health services needed and essential, safe, affordable, effective and quality medicines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable and marginalized segments of the population;”²⁹



In 2011, the General Assembly adopted a resolution endorsing a political statement in which UN Member States recognize:

“[the] critical importance of affordable medicines, including generics, in scaling up access to affordable HIV treatment, and further recognize that protection and enforcement measures for intellectual property rights should be compliant with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all;”³⁰

In 2011, the UN General Assembly adopted a resolution on the prevention and control of non-communicable diseases,

“45(p) Promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of non-communicable diseases, including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities;”³¹

In 2003, the UN General Assembly said that it was:

“Fully aware that the failure to deliver antiretroviral treatment for HIV/AIDS to the millions of people who need it is a global health emergency”

And that it:

“6. Further calls upon States to pursue policies, in accordance with applicable international law, including international agreements acceded to, which would promote... (a) The availability in sufficient quantities of pharmaceutical products and medical technologies used to treat pandemics such as HIV/AIDS, tuberculosis and malaria or the most common opportunistic infections that accompany them;”³²

In 2013, the Secretary-General reported an update on progress from the 2011 Political Declaration on HIV/AIDS, concluding:

“Reducing drug costs further will require effective use of the flexibility available under international intellectual property provisions, preserving the availability of generic alternatives to branded drugs and increasing the capacity of low-income and middle-income countries, in particular in Africa, to develop and manufacture essential medicines. All parties involved in negotiating new free trade agreements should avoid proposing or agreeing to provisions that

could diminish the ability of low-income and middle-income countries to obtain a reliable supply of affordable medicines.”³³

Immediately on the heels of the passage of the TRIPS Agreement, human rights experts voiced concerns about the impact of this new international IP regime on the enjoyment of human economic, social and cultural rights.³⁴ The 2001 Human Development Report raised concerns surrounding the risks inherent in the existing IP regime on access to medicines.³⁵ And from as early as 2001, the UN Office of the High Commissioner for Human Rights (OHCHR) has expressed concerns about the negative impact of TRIPS on achievement of the human right to health.³⁶ Reflecting then-emerging developments in international trade and IP law, the *UNAIDS/OHCHR International Guidelines* were substantially revised to specify state practices aimed at simultaneously advancing innovation and access to medicines to strengthen the required human rights response to the pandemic:

- increasing funds allocated to the public sector for researching, developing and promoting therapies and other technologies, and encouraging the private sector to undertake such R&D and making the results available at affordable prices, with particular attention in both instances to the health needs of developing countries;
- mobilizing funds for the purchase and distribution of such technologies, accompanied by procurement policies favouring the purchase of generics where these are less expensive;
- ensuring that international agreements, such as those dealing with intellectual property, do not impede access to health care technologies; and
- ensuring that their domestic legislation incorporates to the fullest extent any safeguards and flexibilities in such international agreements that may be used to promote and ensure access to medicines, diagnostics and related technologies, and that they make use of these safeguards to the extent necessary to satisfy their domestic and international obligations in relation to human rights; and
- reviewing said international agreements to ensure their consistency with human rights obligations, and amending them as necessary.³⁷

UN special rapporteurs – on the right to health and in the field of cultural rights – have also urged proactive steps to balance the application of IP laws with human rights obligations, with a focus on using existing TRIPS flexibilities. In 2001, the Special Rapporteur on the right to health undertook a mission to the WTO, against a background of concerns about the impact of TRIPS on the right to health, in light of the lack of access to antiretroviral medicines in low- and middle-income countries. His resulting report urged greater attention to the human rights dimension and greater attention to the promotion of TRIPS-compliant flexibilities and the avoidance of TRIPS-plus provisions.³⁸ In 2006, the

Special Rapporteur issued a second report focusing both on states' duties with respect to ensuring medicines are available, accessible, culturally acceptable and of good quality and the responsibilities of pharmaceutical companies as well.³⁹ The Special Rapporteur codified his guidance to pharmaceutical companies in 2008, including with respect to neglected diseases and patents and licensing.⁴⁰ In his 2009 report to the UN General Assembly, the Special Rapporteur explored the ways TRIPS flexibilities have and have not been incorporated into national patent laws of developing and developed countries. He further analyzed free trade agreements and the effect of TRIPS-plus requirements on access to medicines. He called on developing countries to use TRIPS flexibilities and to refrain from entering into trade agreements with "TRIPS-plus" provisions.⁴¹ In 2014, the Special Rapporteur called for an international mechanism for holding transnational corporations liable for violations of the human right to health. He also called for a review of the current system of international investment agreements and investor-State dispute settlement.⁴² His critique of ISDS has recently been echoed by the Report of the Independent Expert on the promotion of a democratic and equitable international order.⁴³

More recently, the Special Rapporteur in the field of cultural rights reported that "[t]he human rights perspective demands that patents do not extend so far as to interfere with individuals' dignity and well-being."⁴⁴ She noted that patent policies and practice may divert research priorities away from matters of greatest public concern, that IP can be ineffective in stimulating necessary R&D, that there are alternative mechanisms for stimulating research, and that patents can get in the way of producing an improved dependent technology.⁴⁵ The Special Rapporteur called upon countries to promote the right to science and culture through exclusion, exceptions, and flexibilities.⁴⁶ The Special Rapporteur made a particularly strong set of recommendations highlighting the deprivations that can occur through patent exclusivity, and the importance of broad diffusion of technological advances. She concluded that implementing unreasonably strong patent protection may constitute a violation of human rights and reaffirmed that there is no human right to patent protection in article 15 of ICESCR. She also called for exploration and adoption of alternative incentive model for technological innovation.⁴⁷

ii. Other relevant work and initiatives

The UK Commission on Intellectual Property Rights

This Commission produced a lengthy report, 'Integrating Intellectual Property Rights and Development Policy' in 2002, with recommendations aimed at aligning IP rules with development objectives in developing countries. It pointed out that the current IP system played almost no role in stimulating research on diseases prevalent in developing countries unless there were a corresponding significant

market in rich countries. Instead, the IP system increased costs, negatively impacting access to health technologies needed by less affluent countries.⁴⁸

“Our starting point in this analysis is that healthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare.”⁴⁹

The UK Commission endorsed the regular use of parallel importation and compulsory licensing by developing countries in order to secure access to more affordable medicines.⁵⁰ It also urged that countries adopt the early working exception and provide only minimum forms of data protection to facilitate marketing approval of follow-on generic products.⁵¹ Finally, it urged developing countries to adopt maximum strictness in applying patenting standards and incorporating flexibilities in domestic legislation:

“The underlying principle should be to aim for strict standards of patentability and narrow scope of allowed claims, with the objective of:

- *limiting the scope of subject matter that can be patented*
- *applying standards such that only patents which meet strict requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made*
- *facilitating competition by restricting the ability of the patentees to prohibit others from building on or designing around patented inventions*
- *providing extensive safeguards to ensure that patent rights are not exploited inappropriately.”⁵²*

Global Commission on HIV and the Law

A far-reaching critique of the public health impacts of the TRIPS Agreement is found in the final report of the independent Global Commission on HIV and the Law.⁵³ From the evidence brought before it, the Global Commission concluded:

“In spite of their potential benefits, TRIPS flexibilities have proved insufficient in obviating the shortages of affordable medicines that TRIPS itself has contributed to creating. The TRIPS Agreement, on paper, affords flexibility as to how its obligations are implemented by national governments. Nevertheless, in practice, the attempts by low- and middle-income countries to



use measures to promote access to affordable medicines have been fraught with difficulty and met with retaliation and opposition from some high-income countries and corporations.”⁵⁴

The Global Commission noted the upswing in TRIPS-plus provisions and pressures, including in the IP enforcement arena.⁵⁵ It concluded that the patent system, as underpinned by TRIPS, was not delivering promised innovation.⁵⁶ It noted promising proposals including innovation prize funds, a binding international treaty on R&D and open source drug discovery.⁵⁷ In addition to recommending the establishment of this Secretary-General’s High-Level Panel, the Commission called on developed countries to cease making TRIPS-plus demands, and on developing countries to refuse such demands, including requests to formally ratify the Paragraph 6 System. Even more boldly, the Commission called for an immediate moratorium on the enforcement of the TRIPS Agreement.⁵⁸ With respect to innovation, the Commission stated:

“TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available for the poor, including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritizing the most promising approaches including a new pharmaceutical R&D treaty and promotion of open source discovery.”⁵⁹

Several other civil society and academic bodies outside of intergovernmental institutions have highlighted the need for coherence between trade laws and public health objectives. One of the first such initiatives emerged in 1999, from a conference convened by Health Action International, Médecins Sans Frontières, and Consumer Project on Technology on the eve of the Seattle WTO ministerial conference, drew up the [Amsterdam Statement](#), which urged WTO Members to include public health as a priority in trade negotiations, and urged national governments to develop new and innovative mechanisms to ensure funding for R&D for neglected diseases.⁶⁰

More recently, the Global Congress on Intellectual Property and the Public Interest adopted the [Washington Declaration on IP and the Public Interest in 2011](#).⁶¹ The Declaration noted that

“Markets alone cannot be relied upon to achieve a just allocation of information goods — that is, one that promotes the full range of human values at stake in intellectual property systems. This is clear, for example, from recent experiences in the areas of public health and education, where intellectual property has complicated progress toward meeting these basic public needs.”

With respect to the patent system, the Washington Declaration concluded:

“In a period of rapid technological change, the patent system has serious problems. In some industries, very low patenting standards and a proliferation of patents of questionable validity have fueled a culture of competition by intimidation and litigation, rather than innovation. Even when patentability requirements are applied strictly, the international patent system has become too rigid and too unitary to accommodate the diverse needs of a complex world. A more effective and manageable system for fostering technological and scientific innovation should be built around a more diverse structure of incentives for innovation.”

Another initiative, Uniting to Combat Neglected Tropical Diseases, issued its [London Declaration](#) focusing largely on supporting increased innovation in the NTDs space.⁶² Another proposal, focusing on interpretation regulatory options States retain under TRIPS norms, is the [Max Planck Society Declaration on Patent Protection: Regulatory Sovereignty under TRIPS](#).⁶³ This Declaration states:

“The patent system’s overall acceptance rests on a delicate interplay of privileges and responsibilities. As a regulatory institution, its operation must also accommodate other public policies and interests, such as environmental protection, biological diversity, health care (including managing the risks of pandemics), nutrition, food security, technological and scientific progress, education and security.”⁶⁴

A key deduction of the above Declaration is that patent systems can be differentiated with respect to fields of technology, for example pharmaceuticals, and that the principle of non-discrimination does not apply with respect to TRIPS Article 30 and 31 flexibilities.⁶⁵

Part B. Literature review of current initiatives and proposals using new mechanisms for incentivizing innovation and accomplishing access to health technologies

Section B of the background paper comprises of a literature review of models and ideas that have already been put forward in various forums that propose alternative mechanisms to ensure increased innovation of needed health technologies and improved access to the same. For the main part, the access components of these proposals are essentially voluntary or contractual, meaning that they do not involve systems-wide reforms to address the misalignment or incoherence of rights of inventors, international human rights law, trade rules and public health. Thus, this section does not further develop many of the IP reform proposals outlined in the preceding section.

To give structure to the variety of innovation initiatives presented in this Section, the Secretariat in this Section has drawn substantially on a methodology and survey of existing and proposed innovation initiatives described in a forthcoming publication by the organization, Universities Allied for Essential Medicines (UAEM), *RE:ROUTE – A map of the alternative biomedical R&D landscape* (2016). This publication is the most recent and comprehensive report of this kind – of which the Secretariat is aware. However, like the authors of the UAEM publication, the mapping undertaken in this background document is not intended to be fully comprehensive – indeed there is no ‘master list’ of such existing initiatives. Nor does it seek to make conclusive judgments on the merits of initiatives included. While some strengths and criticisms associated with some of the initiatives are highlighted, the main purpose of the paper is rather to present a snapshot of the variety of alternative innovation models to address innovation challenges the High-Level Panel is being asked to address.

In its publication, UAEM found 49 existing initiatives and 32 proposed initiatives. To be included in the study, initiatives had to be driven by the needs of patients globally, and use one or more of the following innovation principles/mechanisms (other than purely private sector, commercially oriented R&D funds):

- **Push Mechanism [PUSH]** – Direct funding for R&D, often in the form of a grant, as well as indirect incentives, such as tax breaks and in-kind contributions, that help finance R&D upfront and thus mitigate the R&D investment required; they are given independently of the results of such research.
- **Pull Mechanism [PULL]** – Mechanisms to incentivize R&D activities through the promise of financial rewards once specified objectives or milestones have been met, creating viable market demand. It includes prizes, priority review vouchers (PRVs), advanced market commitments (AMCs), and cash payments.

- **Financial Pooling Mechanism [\$POOL]** – Pooling of funds that are aggregated and managed jointly by an established entity, typically a board or committee, to be allocated based on priority setting in order to distribute risk and finance biomedical R&D. The goal of pooled funding is to address inefficient flow and volatility of funds as well as poor allocation of and lack of sufficient resources.
- **IP Pooling Mechanism (IP/POOL)** – Pooling of IP: typically via a patent pool, an agreement between two or more patent owners to pool their patent rights and license the rights to use these patents together to one another as well as third parties often with the requirement of royalties being paid. The goal of patent pools is typically to enable access to biomedical discoveries and encourage downstream competition by simplifying and improving voluntary and cooperative licensing negotiations.
- **Collaborative Initiative [COLLABORATIVE]** – An R&D initiative that involves a network, consortium, or partnership between two or more of any academic or research institutions, non-profit organizations, NGOs, governments, government entities, or members of the private sector including biotech and pharmaceutical companies. Exchange of information and data pooling is often regulated via Material Transfer Agreements and restricted to within the involved entities unless the initiative is also open.
- **Open Initiative [OPEN]** – R&D initiatives that apply open source, open access, open data, or open knowledge principles. Interested parties are able to contribute knowledge or know-how, data, technology, etc. to be shared in the public domain and, in the case of open source, in coordination with patent-free research. Open initiatives provide literature and/or other information such as biomedical data, typically digital or online, often without any fee or cost and without any copyright and licensing restrictions such as royalties, in order to encourage further access to and reuse of this information and facilitate open collaboration and exchange in biomedical R&D (Creative Commons, 2011). Open access typically pertains to making publications freely available; open source typically pertains to making licenses or IP freely available; and open data typically refers to making data, methods, and/or tools freely available.
- **Delinkage (DELINK)** – a combined R&D and access initiative that separates funding mechanisms for the costs of medical R&D from the cost of producing the medicines by disallowing market exclusivity and promoting competition for quality assured health technologies.
- **Access Licenses (ACCESS LICENSES)** – an access mechanisms that fosters competitive production and/or more affordable pricing via voluntary licenses while still preserving underlying IP rights; differs from a IP/POOL because it doesn't aggregate IP rights from multiple right holders.
- **IP Reform (IP REFORM)** – a proposal to amend the TRIPS Agreement and other IP rules to improve access to new health technologies.⁶⁶



This Section also summarizes some additional important initiatives including the proposed Essential Health and Biomedical R&D Treaty, the AllTrials Campaign, the Ross Fund, and others. This Section is organized to highlight selected examples of existing and proposed initiatives (attempting to include a mix of initiatives involving public and private partners; from low-, middle- and high-income countries; which address innovation gaps for medicines, vaccines, diagnostics and other health technologies; and which represent both successes and some of the shortcomings), while referencing some of the other known initiatives as well. As the authors of the UAEM report have clarified, this paper similarly does not attempt to be comprehensive, nor offer value judgments on the initiatives listed, but merely provide a brief snapshot and overview of *some* of the initiatives existing or already put forward, for the High-Level Panel's information and background.

Existing initiatives

i. Drug discovery and data sharing platforms

The Indian **Open Source Drug Discovery** (OSDD) [OPEN] initiative, launched in 2008 by India's Council of Scientific and Industrial Research Team to address novel therapies for neglected tropical diseases, promotes collaboration and an open approach to IP through crowdsourcing and social networking as well as open access repositories. Focusing on translational research and funded in part by \$46 million from the Government of India, the OSDD requires collaborators not to take from the research commons or to privatize resulting products and further allows right holders to donate or license their IP for non-exclusive use. Principal work to date has focused on TB and malaria.⁶⁷

The **Collaborative Drug Discovery** (CDD) initiative [OPEN], founded in 2004 by Eli Lilly, creates a secure, cloud-based tool to enable neglected disease and other researchers with diverse areas of expertise to collaborate and share compounds and drug discovery data via an online database. Two-hundred-fifty researchers from 58 laboratories, including DNDi, Johns Hopkins University, Pfizer, The Rockefeller University, Seattle BioMed, and the University of Pennsylvania use the CDD Vault, its drug discovery data-sharing platform. A project near completion is the Kietoplastid Drug Development consortium focused on promising anti-trypanosomatid drug discovery, although there are other initiatives on anti-TB and anti-malarial compounds as well. According to a 2013 article, "CDD has effectively lowered the 'activation barrier' for data archival of low, medium, and even high throughput experiments."⁶⁸

The **WIPO Re:Search** initiative [COLLABORATIVE & OPEN], briefly introduced in Part A, involves 93 members from the public and private sector and provides secure, online, open, and collaborative access for researchers to IP, pharmaceutical compounds, research technologies, know-how, regulatory

data, and other assets for upstream work on neglected diseases, TB, and malaria. Thus far, it has brokered 70 partnerships across 15 diseases. WIPO Re:Search does not restrict IP ownership but does define access terms for LDCs.⁶⁹ The initiative recently underwent a comprehensive review that concluded that no new medicines had actually yet been developed but that there had been immense progress in access to research. The review recommended closer ties with product development partnerships, a firmer financial foundation, an upgrade of its database, and better responsiveness to and capacity building to meet the needs of researchers in developing countries.⁷⁰

Additional drug discovery and data sharing initiatives:

- **Dialogue for Reverse Engineering Assessment and Methods** (started 2006) (PULL + OPEN): Data sharing and crowdsourcing open source platform with an emphasis on computing, including for cancer research.⁷¹
- **InnoCentive** (started 2001) (\$POOL + OPEN): Open innovation network for crowdsourcing with a non-profit area focused on accepting commissions to research and address development problems including those related to neglected health needs.⁷²
- **Structural Genomics Consortium** (started 2004) (COLLABORATIVE & OPEN): open access, collaborative network focused on less well studied areas of the human genome (pre-competitive structural biology research), involving hundreds of universities and nine global pharmaceutical companies and requiring public domain access and delay in claiming IP.⁷³
- **Cambia's Patent Lens and Initiative for Open Innovation** (started 1992) – (OPEN): International non-profit research organization providing open access and collaborative public resources for innovation via its Patent Lens and IOI initiatives; it seeks to democratize innovation by making patent systems more transparent, inclusive, and navigable and promoting Biological Open Source licensing.⁷⁴
- **TDR Targets** (started by WHO, UNICEF, UNDP, World Bank) (OPEN): collaborative knowledge-sharing platform with an open access database to facilitate the identification and prioritization of drugs and drug targets for neglected disease pathogens.⁷⁵
- **The Synaptic Leap** (started in 2006) (OPEN): Open and collaborative network of online research communities that connect and enable open source biomedical research and drug discovery with major focus on schistosomiasis, malaria, toxoplasma, and TB.⁷⁶
- **Kaggle** (started in 2010) (OPEN): online collaborative platform for data-mining and predictive modeling competitions via crowdsourcing; world's largest community of data scientists trying to bridge the gap between data problems and solutions.⁷⁷
- **AllTrials Campaign** (started in 2013) (OPEN) calls for all past and present clinical trials to be registered and their results reported. The intent is to allow access to clinical data to protect human

subjects, to inform doctors and researchers and allows follow-on and confirmatory research, to aid drug discovery, and to reduce duplicative trials and other inefficiencies.⁷⁸

ii. Drug discovery incentives

Prizes

The **Longitude Prize Open** initiative (PULL), which launched in 2014, provides an ex-ante, £10 million inducement prize to be awarded to the submission considered most impactful and feasible for a competitive antimicrobial resistance innovation, specifically a point-of-care diagnostic that will help conserve antibiotic use.⁷⁹ The prize is being run by Nesta and is supported by Innovate UK as a funding partner, along with support from others. Some critics argue that this initiative focuses too much on science, ignoring larger political and social barriers that might impede adequate supply and distribution.

The **X-Prize Foundation** (PULL), partnered with the Bill & Melinda Gates Foundation in 2008, to plan the launch of a \$5-\$20 million, milestone inducement prize to spur innovation on an improved TB diagnostic tool. The prize morphed into a \$10 million Qualcomm Tricorder XPRIZE which is currently underway and which seeks a device that can accurately diagnose a set of health conditions, such as diabetes, atrial fibrillation, stroke, tuberculosis, chronic obstructive pulmonary disease, pneumonia and Hepatitis A. They must also capture real-time health metrics, such as blood pressure, respiratory rate and temperature.⁸⁰

Additional prize initiatives:

- **Prize4Life Foundation** (started in 2006) (PULL + OPEN) offered a milestone inducement prize, crowdsourcing, and a data sharing platform for cures and treatment of amyotrophic lateral sclerosis.⁸¹
- **EU Vaccine Prize** (initiated by the European Commission in 2012) (PULL) offered a €2 million end product inducement prize to be awarded for a vaccine cold chain innovation. The prize was awarded in 2014.⁸²

Tax subsidy/priority review incentives

The **Pneumococcal Vaccine Advance Market Commitment** (AMC) (PULL) was launched by donors in 2009 to promote vaccine research and product development, initially \$1.5 billion for pneumococcal diseases, by guaranteeing a subsidized market, at a given price, for products that met the target product profile. The AMC concept called for the broader creation of a US\$3 billion market whereby

manufacturers sign legally binding supply offers for purchases by countries and donors for medicines such as HIV, TB, and malaria.⁸³ According to critics, the AMC was applied to two vaccines already in final stages of development, rendering it more of a procurement mechanism than an R&D incentive. The mechanism has also been criticized as too complex and expensive, as favoring large companies, and as resulting in prices much higher than would be achieved via generic competition.

The **FDA Priority Review Voucher** (PRV) (PULL) program was launched in 2008 – any organization that won FDA approval for a new medicine against a defined list of neglected and pediatric diseases was eligible for a transferrable PRV that would allow expedite FDA review of another new drug application. Thus far, only six priority review vouchers have been awarded, with one having been sold for \$245 million. The PRV program has been criticized as a give-away to companies that would ordinarily have developed the product anyway and to companies that did not necessarily undertake the R&D. PRVs are available for medicines marketed already outside the U.S. and may be awarded regardless of whether the newly developed medicine ends up being marketed at all, or at an affordable price.⁸⁴

Additional tax subsidy/priority review incentive initiatives:

- The U.K. **Vaccines Research Relief** initiative (introduced by UK legislation in 2003) (PULL) offers a tax-based incentive to encourage companies to increase their R&D investment on vaccines and treatment for HIV, TB, and malaria.⁸⁵
- The U.S. **Orphan Drug Program** (legislation passed in 1984) (PULL + PUSH) provides additional periods of marketing exclusivity, priority review, R&D grants, tax credits, and other benefits for orphan drug discoveries. Although criticized for leading to high prices, the Program has incentivized a significant degree of orphan drug development.⁸⁶
- The U.S. **Patents for Humanity Awards for Medicine** (introduced by the Patent & Trademarks Office in 2012) (PULL) offers patent review acceleration to encourage development of drugs for neglected health needs by shortening the time it takes to enter the market. Awards go to technologies that help the “less fortunate.”⁸⁷

Innovation fund/platform

The **Ross Fund** (PUSH) was announced by the U.K. in late 2015 to provide funds to develop, test, and deliver new vaccines, drugs, and diagnostics to help combat the most serious infectious diseases in developing countries. It brought together work on anti-microbial resistance, diseases such as Ebola, and neglected tropical diseases. On 25 January 2016, an additional £ 3 billion over the next five years was pledged by the U.K. and the Bill and Melinda Gates Foundation to support the goal of reducing malaria deaths by 90% by 2030.⁸⁸



The **European Developing Countries Clinical Trials Partnerships** (PUSH), started in 2003 and renewed in 2014, funds collaborative research to accelerate the development of new or improved drugs, vaccines, microbicides, and diagnostics against poverty-related and neglected diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials. It also supports capacity building for researchers. It is a public-private partnership between the EU, Europe, and sub-Saharan Africa. The EU has pledged €683 million over 10 years. During its first phase EDCTP funded 241 projects in 30 countries and helped train hundreds of African scientists and students. The major critique is that EDCTP is a best practice with respect to clinical trials but that it has yet to accomplish integration of national clinical trials programs.⁸⁹

The **Bridging Interventional Development Gaps Programme** (PUSH) provides in-kind resources to facilitate drug discovery for both common and rare diseases by small businesses. Successful applicants receive access to U.S. NIH experts and contractors who conduct preclinical studies at no cost to the investigator. There is additional support for synthesis, formulation, pharmacokinetic and toxicology services in support of investigational new drug applications to the U.S. FDA. As of fall 2015, 18 IND applications had been cleared for projects with BrIDGs-supported data and 14 projects have been evaluated in clinical trials. The sole critique thus far is that applicants can out-license their compound and still receive BrIDGs' support.⁹⁰

Additional tax subsidy/priority review incentive initiatives:

- The **Global Health Innovative Technology Fund** (launched in 2013) (PUSH) is a \$100 million Japanese private-public initiative to fund research on neglected diseases.⁹¹
- The **Sustainable Sciences Institute** (founded in 1998) (PUSH) supports scientific and public health communities with grants and other contributions to advance in-country R&D in resource-poor countries and capacity building for various diseases including Chagas disease, dengue fever, and onchocerciasis, especially in Latin America.⁹²
- The **Global Health Investment Fund** (launched in 2013) (PUSH) is a \$108 million social impact investment fund that provides milestone payments and royalties to finance drug, vaccine, and diagnostic development and to support global access agreements via “mezzanine” debt funding, with returns reinvested in global health R&D.⁹³
- **Humanitarian Assistance for Neglected Diseases** (founded by Genzyme in 2006) (PUSH) focuses on collaborative, non-commercial drug discovery and development by identifying, evaluating, and managing projects and partnerships focused on neglected diseases, with IP going to non-profit partners.⁹⁴



Venture philanthropy for drug discovery and development

CQDM (COLLABORATIVE + PUSH), founded by the Quebec's and Canada's national governments and 12 pharmaceutical companies in 2008, is a pre-competition research consortium for funding development of breakthrough tools and technologies that enhance biopharmaceutical R&D productivity and accelerate the development of safer and more effective drugs. All business partners share the costs of R&D and the resulting benefits. Investigators retain full ownership of all generated IP. CQDM has raised \$65 million and supported 50 research projects involving a network of 610 researchers, which have a 94% success rate.⁹⁵

Cystic Fibrosis Foundation Therapeutics (CFFT) (COLLABORATIVE + PUSH), established in 2000, is a non-profit collaborative network for drug development on cystic fibrosis employing venture philanthropy. This initiative has funded projects leading to innovative new therapies in the drug development pipeline. CFFT offers matching research awards, primarily milestone-driven, plus access to a specialized network of cystic fibrosis research centers. Upon registration of a CFFT supported medicine, CFFT receives multiples of its investments or a royalty based on sales that it reinvests in new products. It has conducted more than 100 clinical trials. There are concerns that medicines discovered tend to be overpriced and that the Foundation has a conflict of interest at the expense of CF patients.⁹⁶

Additional venture philanthropy for drug discovery and development initiatives:

- **Dementia Discovery Fund** (announced by the UK government in 2015) (\$POOL + PUSH) is a \$100 million venture philanthropy capital fund designed to accelerate pooled-risk research on a cure for dementia. When a project is successful, companies will bid to develop it further providing returns to initial investors.⁹⁷

iii. Drug licensing: patent pools and related initiatives

The **Medicines Patent Pool** (MPP) (IP/POOL & ACCESS LICENSES) was established in 2010 with funding from UNITAID. It originally focused exclusively on HIV treatments, implementing voluntary licensing of critical IP from right holders and out-licensing to generic pharmaceutical sales for manufacturer, sale, and use in low- and middle-income countries. It has recently expanded its mission to include Hepatitis C and Tuberculosis medicines. Originator licensors ordinarily receive a royalty. The MPP seeks a number of standard terms, including those on quality, permissible use of oppositions, invalidations, and compulsory licenses, and full disclosure of licenses. The MPP has reached agreement with 6 patent holders and 10 generic companies on 12 antiretrovirals directly benefitting countries that are home to 87-93% of people living with HIV in the developing world. The MPP, together with UNITAID, DNDI, and

CHAI is a partner in the Paediatric HIV Treatment Initiative, and it maintains a comprehensive patent database. Its licenses are estimated to save over \$1 billion through 2028. Although the MPP has since received much of support and approval for facilitating certain combinations of medicines and for expanding access, some civil society critics have been quite vocal about exclusion of several middle-income countries and the impact of the Pool's voluntary licenses on political will to adopt and use other TRIPS-compliant flexibilities.⁹⁸

The GSK Pool for Open Innovation against NTDs (POINT) (IP/POOL + OPEN) was established in 2009. GSK sought to encourage innovation that targets diseases of the developing world. GSK's open innovation strategy was designed to promote change by (1) sharing its expertise and resources with scientists from around the world by enabling them to conduct their research projects in the open lab at their Tres Cantos Medicines Development Campus which is focused on discovering new medicines in diseases of the developing world, (2) being more open with data and research to help stimulate research outside GSK, and (3) being more flexible with IP and know-how. POINT has now been rolled into WIPO Re:Search.⁹⁹

iv. Drug advancement: larger Private-Public Partnerships (PPPs) or organizations that house multiple innovative R&D initiatives

The **European Vaccine Initiative (EVI) (COLLABORATIVE + PUSH)**, founded in 1998, is a non-profit PPP designed to foster an environment that permits potential vaccines to undergo clinical trials and that results in affordable vaccine access for low-income populations. EVI works on vaccine development, coordination, harmonization, R&D services, capacity strengthening, and policy activities. EVI initially focused on malaria and developed 24 malaria antigen combinations in 32 vaccine formulations. Several candidates are now in late stage development. EVI has supported a collaborative project, **TRANSVAC**, designed to create a network for vaccine R&D across a broad range of diseases. The effectiveness of EVI has been undermined by European governments' withdrawal from funding state-owned vaccine production facilities for economic reasons.¹⁰⁰

The **Sabin Vaccine Institute PDP (PUSH)**, founded in 2000, focuses on vaccine-preventable and NTDs, including hookworm, schistosomiasis, and Chagas disease. Existing capabilities include: product development, technology transfer and manufacturing, epidemiological and clinical studies, and ethical and regulatory approvals. Although Sabin has developed a comprehensive, relatively low-cost model for non-profits vaccine R&D, its funding sources may not be diverse enough to reduce transaction and up-front costs.¹⁰¹



The **International AIDS Vaccine Initiative** (IAVI) (COLLABORATIVE + PUSH + PULL], founded in 1996, is a global non-profit working to develop an AIDS vaccine through its own research, development of consortia and partnerships, funding of external work, and product development services. It houses both a PDP and an innovation fund. It has built research labs in five African countries and in India. IAVI engages in policy and social science research, observation epidemiology, and clinical trials and seeks an appropriate role in the broader HIV and AIDS prevention and treatment response.¹⁰²

The **Program for Appropriate Technology in Health** (COLLABORATIVE + PUSH), founded in 1977 to address women's health issues but expanded in 2014 to address a broader range of health technologies. It is a large organization known for partnering with the private sector. It includes the Malaria Vaccine Initiative, the Meningitis Vaccine Project, a Rotavirus Vaccine Access and Delivery Program, a Pneumococcal Vaccine Project, a Japanese Encephalitis Program, and the Institute for OneWorld Health, which is focused on orphan drugs and NTDs. PATH has its own state-of-the-art laboratory and a product development shop. It is partially responsible for the development of the first successful malaria vaccine.¹⁰³

The **African Network for Drugs and Diagnostics Innovation** (COLLABORATIVE + PUSH) was launched in 2008 and was promoted by African governments to help develop African-led product R&D innovation and to enhance Africa R&D capacity and infrastructure. The plan called for a \$600 million endowment fund and other donations to generate sustainable financing of \$30 million annually. ANDi has identified multiple centers of excellence; 2 standalone projects and 5 network projects have been announced.¹⁰⁴

Additional larger PPPs or organizations that house multiple innovative R&D initiatives:

- The **International Vaccine Initiative** (operating as an independent organization in 1997) (PUSH) houses several PDPs focused on vaccine for cholera, typhoid, dengue fever, and other disease affecting the health of children in developing countries.¹⁰⁵
- The **Critical Path to Tuberculosis Drug Regimens** (COLLABORATIVE + Open) is a PPP with an open source and open innovation collaborative database and drug development coalition to speed development of new and markedly improved TDB drug regimens.¹⁰⁶
- **Bioventures for Global Health** (founded in 2004) (COLLABORATIVE + PULL) is a non-profit that provides incentives and foster collaboration and partnerships in various areas of global health. It supports WIPO Re:Search.¹⁰⁷



v. Drug development

Disease-specific PDPs offering alternative approaches and business models

Medicines for Malaria (MMV) (COLLABORATIVE & ACCESS LICENSES) was founded in 1999 with \$4 million seed money and is now the leading PDP in the field of antimalarial drug R&D. MMV has over 65 projects and 9 new drugs in clinical development. It is comprised of an extensive partnership network of over 375 pharmaceutical, academic, and endemic-country partners in 50 countries. MMV has developed and registered four new medicines. MMV claims to promote and protect access and affordability via social responsibility agreements with partners that include exclusive, transferrable, worldwide licenses for programme and background IP and royalty-free licenses for malaria endemic countries. The MMV needs to expand its number of donors and to address the challenges of access.¹⁰⁸

The **TB Alliance** (COLLABORATIVE & ACCESS LICENSES) was founded in 2000 and based in NYC and Pretoria, SA. It is dedicated to the discovery and development of better, faster-acting, affordable drugs for TB, including drug-resistant TB. The TB Alliance manages a portfolio of candidate TB compounds from the public and private sector, using a variety of licensing and partnership agreements. It has a robust community engagement program. The Alliance currently manages more than 20 projects involving 9 novel classes of TB medicines. It is currently focusing on development and proof of novel TB drug regimens.¹⁰⁹

Additional disease-specific PDPs challenging current R&D system:

- **International Partnership for Microbicides** (founded in 2002) (COLLABORATIVE) focuses on preventing HIV and contraception. It evaluates promising compounds, designs optimal formulations, conducts pre-clinical and clinical trials, identifies regulatory pathways, establishes manufacturing and distribution capacity, and engages in advocacy.¹¹⁰
- **Aeras Global TB Vaccine Foundation** (founded in 2003) (COLLABORATIVE) is a nonprofit biotech firm and PDP focused on TB vaccine development. It has conducted over 30 clinical trials of six experimental vaccines.¹¹¹
- **TuBerculosis Vaccine Initiative** (founded in 2008) (COLLABORATIVE) is a PDP focused on the development and delivery of a TB vaccine. It has 50 partners and has delivered 6 vaccine candidates.¹¹²



PDPs working across diseases

Drugs for Neglected Disease Initiative (DNDi) (COLLABORATIVE & ACCESS LICENSES), established in 2003, DNDi focuses on drug development for neglected diseases and pediatric HIV without an in-house product development capacity. It has focused on building regional, disease specific platforms. While primarily focused on R&D, DNDi also engages in fundraising and advocacy and has a robust access strategy based on an IP/access strategy that focused on royalty-free and non-exclusive licensed access and freedom for follow-on research and further product development. DNDi intends to deliver 11-13 new treatments by 2018; so far it has delivered six treatments for malaria, sleeping sickness, visceral leishmaniasis, and Chagas. DNDi's new business plan is to introduce a more flexible portfolio, to focus on additional health needs, and to advance more open and collaborative models of innovation. DNDi has 7 founding partners, 130 partnerships, and 3 clinical trial platforms.¹¹³

Fund for Innovative New Diagnostics (FIND) (COLLABORATIVE) was founded in 2003 and is focused on development of diagnostic tools for poverty-related diseases; it has no in-house production capacity. FIND, engaging over a 150 partners, operates as a facilitator, mobilizer, and bridge builder to support quality-assured diagnostic solutions and linkage to care across the value chain. FIND claims to have developed a novel commercial model based on a segmented IP policy that overcomes typical barriers to access while still motivating the best biotech companies to participate. FIND has delivered 11 new tests, conducted numerous clinical trials, identified biomarkers, and facilitated regulatory clearance. FIND continues to evolve to a changing technical landscape and to new opportunities.¹¹⁴

Additional PDPs working across diseases

- **Infectious Disease Research Institute** (established in 1993) (COLLABORATIVE) is a PDP focused on drug development for neglected diseases.¹¹⁵
- **Medicines Development for Global Health** (founded in 2005) (COLLABORATIVE) is a PPP focused on drug development for infectious disease such as onchocerciasis with in-house production capacity.¹¹⁶
- **European Commission's Innovative Medicines Initiative** (launched in 2008) (COLLABORATIVE + PUSH) is a European PPP focused on drug developed for neglected needs in both LMICs and HICs and provides grants for research. It is the world's largest PPP in the life sciences with a planned budget of \$3.3 billion 2014-24.¹¹⁷
- **UCSF/UCSD Center for Discovery and Innovation in Parasitic Diseases** (founded in 1985) (Collaborative): a NTD-focused drug discovery and development research center.¹¹⁸

Proposed initiatives¹¹⁹

vi. Drug discovery and data sharing platforms

Exploiting the Pathogen Box (COLLABORATIVE + OPEN + ACCESS LICENSES) is a CEWG demonstration project, using open source collaboration to accelerate drug development in diseases of poverty. It hopes to provide diverse compounds against a range of pathogens free of charge to researchers with the understanding that they will be placed in the public domain. With an expected budget of \$11.5 million, there is not yet an explicit guarantee of affordability, but there is an expectation that there will be equitable licensing policies.¹²⁰

Establishing a Drug Discovery Platform for Sourcing Novel Classes of Antibiotics (PULL + OPEN) is was a CEWG proposal, promising milestone prizes for early stage antibiotic development, non-exclusive licensing and/or patent buyouts for promising antibiotics, and an open source platform to share intellectual property and data. The research will focus on natural molecules. Critiques question the practicalities of patent buyouts, and disincentives for follow-on research.¹²¹

Additional drug discovery and data-sharing platforms

- **Building a Diagnostic Innovation Platform to Address Antibiotic Resistance** (IP/POOL + PUSH + PULL + ACCESS LICENSE), a CWEG proposal, creates a diagnostic innovation platform to address antibiotic resistance. It includes a proposal for a specimen bank, a patent portfolio license, and a clinical trial network.¹²²

vii. Drug discovery incentives

Prizes

The **Bangladesh, Barbados, Bolivia and Suriname Open Source Dividend** (PULL & ACCESS LICENSES) proposes an open source dividend and milestone prizes to reward openness and sharing of knowledge, materials, and technologies as a component of larger innovation inducement prize efforts. There are five sub-proposals relating to a diagnostic test for TB, new cancer treatments, new Chagas treatments, a prize fund based on a percentage of donor assistance for health, and a priority medicines and vaccines prize fund. The proposal has been criticized for not addressing the practical difficulties of managing prize systems and rewards and for perhaps diverting funding from treatment programs.¹²³

Additional prize initiatives

- **Medical Innovation Prize Fund and Prize Fund for HIV/AIDS** (Pull & DELINK) is proposed U.S. legislation for a patent buyout end product prize fund (up to \$80 billion/year) to delink R&D costs from drug prices. It provides for a non-voluntary replacement of patent monopolies with prizes calculated on positive health impact. Its political feasibility has been questioned.¹²⁴

Tax subsidy/priority review incentives

The **Neglected Disease Tax Credit Proposal** (PUSH) would offer tax incentives to subsidize and encourage R&D on neglected diseases, specifically by large companies. It offers a variation of the Orphan Drug Tax Credit – a 50% credit for pre-clinical R&D, but also requires a donation of IPRs to the treatment to a neglected disease organization. The incentives offered, especially in the absence of tax credits for clinical trial costs and without retained IPRs in affluent markets, is expected to be too low to incentivize innovator companies.¹²⁵

The **Options Market for Antibiotics** proposal (PULL) offers market-based incentives across the medicines life cycle as a form of insurance against profitability risks. Among other features, it might offer a guaranteed subsidized market funded by donors. Properly valuing pipeline antibiotics based on incomplete data and the risk of excessive premium pricing have been raised as critiques.¹²⁶

Innovation fund/platform

The **Health Impact Fund** (HIF)(PULL + DELINK) proposes using prize incentives as an alternative to patent protection in order to delink the price of a health product and the cost of R&D through pay-for-performance mechanisms. Participation in the HIF is voluntary and there is a 10-year payout linked to health outcomes with a cost of approximately \$6 billion/year. The HIF proposal does not require relinquishment of IP and allows the product developer to sell non-competitively but at a no-profit price. The proposal has been critiqued for not allowing open licensing and generic competition to further decrease prices.¹²⁷

WHO Pooled Fund for Health R&D in Neglected Diseases (\$POOL + PUSH & DELINK) would establish a voluntary global inter-governmental pooled fund to finance biomedical R&D with an emphasis on neglected health needs. This claims to be the first fund that is committed to delinkage for both commercial and neglected diseases. The proposed fund will need an independent and credible mechanism for priority-setting, monitoring, and coordination of R&D, innovation, fair licensing, and de-linkage, according to DNDi. The sources and amounts of voluntary funding remain uncertain. Studies



on financing and operations are underway and the proposal will be reported to the World Health Assembly in May of 2016.¹²⁸

The Industry R&D Facilitation Fund (\$POOL + PUSH) is a proposed pooled fund to provide secure and flexible funding to select PDPs for R&D in order to encourage greater industry involvement. Up to 80% of R&D funds disbursed by PDPs to industry partners would be reimbursed. It would be a single, central funding mechanism to subsidize industry collaborations across all neglected disease drug development PPPs thereby spreading the risk of investments across projects. There are no proposals concerning IPRs or pricing of resulting medical technologies nor about key operational and funding issues.¹²⁹

Pilot Pooled International Fund (\$POOL + PUSH) is a proposed WHO-managed pilot pooled international fund of \$60 million to finance selected demonstration projects for both neglected and commercial diseases. It would fund open knowledge innovation and implementation for global biomedical R&D through voluntary contributions. It would delink the cost of R&D from the price of subsequent products starting with the four currently accepted CEWG demonstration projects. The Fund would also support a process for selecting priorities through the health R&D observatory, which would monitor the R&D funding landscape globally. There are questions about the likely sufficiency of voluntary contributions and multiple question about the funds political feasibility, added value, and sustainability.¹³⁰

Additional Innovator Fund/Platform Proposals

- **U.K. AMR Innovation Fund** (\$POOL + PULL + DELINK) proposes either to buyout companies that develop a successful antimicrobial resistance medicine or to pay less to companies while maintaining some control over pricing and distribution. Proposals removes perverse incentives for companies to over-market antimicrobials.¹³¹
- **Global Vaccine Development Fund** (\$POOL + PUSH) proposes to establish a global pooled fund of at least \$2 billion to finance vaccine development targeting neglected diseases and other public health threats and helping researchers across the valley of death (Phase 1 & 2 trials).¹³²
- **The Global Biomedical R&D Fund and Mechanism for Innovations of Public Health Importance** (\$POOL + PUSH?) proposes a consolidated global financing mechanism for public health emergencies of international concern or outbreaks (including neglected diseases, antibiotics, and more recently, Ebola).¹³³
- **The Fund for Research in Neglected Disease** (\$POOL + PUSH + IP/POOL & Access Licenses) proposes a \$6-\$10 billion pooled fund and a patent pool focuses on R&D for NTDs with support from PDPs emphasized. IP for neglected disease medicines would be exclusively licensed back to the pool.¹³⁴

- **Product Development Partnership Financing Facility (\$POOL & PUSH)** is a proposed bond-financed fund to provide support for long-term R&D by PDPs on neglected tropical diseases.¹³⁵
- **PDP-Plus Fund (\$POOL + PUSH)** a proposed pooled fund to support PDPS based on integration of FRIND< IRFF, and PDP-FF proposals.¹³⁶
- **Revolving Fund to Finance R&D for Neglected Tropical Diseases (\$POOL & PUSH)** proposes that initial investments in NTD R&D be reimbursed out of resources generated by successful, financed projects.¹³⁷

viii. Drug licensing: patent pools and related initiatives

Essential Medical Inventions Licensing Agency (EMILA)(IP/POOL) is a non-profit entity created to manage patent pools for medical inventions in order to enable generic competition. Proposed in 2006, but unused to date, EMILA would assist third parties in creating patent pools, manage such pools in a non-discriminatory manner to allow open licensing for supply to developing countries, and move from requiring start-up funding to sustaining funding from fees drawn from licensing royalties. The EMILA would require grant-back rights or licenses with respect to patentable product improvements. EMILA would seek patent rights and data/registration rights. It did not address sharing of know-how and materials. An optional feature is that licensing to EMILA would be a pre-condition to eligibility for innovation prizes.¹³⁸

System of automatic compulsory licensing (IP REFORM + ACCESS LICENSES) was proposed to a Médecins Sans Frontières Revising TRIPS Ideas Contest. One of the contest winners, the automatic compulsory licensing submission proposed that the TRIPS Agreement be amended to allow automatic involuntary licensing of prescription medicines in developing and least developed countries and that royalties would be based on the world market share of a specific country for such new drugs.¹³⁹

Excluding essential medicines from patentability in TRIPS (IP REFORM), a third MSF contest entry, proposed that TRIPS should be revised to be consistent with international human rights obligations by excluding essential medicines from patentability by amending Article 27(3)(a) and Article 7. Essential medicines exclusions would be based on national Essential Medicines lists. The proposal acknowledges that an R&D treaty might be part of the political bargain to help ensure adequate funding for needed R&D.¹⁴⁰

ix. Drug development

Disease-specific PDPs challenging current R&D system

Chagas R&D Accelerator Initiative (COLLABORATIVE + PUSH + PULL + Open + ACCESS), a selected CWEG pilot project, proposed the creation of a coordinated and collaborative Chagas Disease Initiative focused on new biomarkers for testing therapeutic efficacy, a biobank portal, and subsequent development of promising drug candidates. The initiative would use prizes, information sharing, and an equitable access policy. At the downstream end, the initiative would review and proposed regulatory, financial, and procurement policies.¹⁴¹

Additional disease-specific PDPs challenging current R&D system

- **Development of Class D CPG ODN (D35) as an Adjunct to Chemotherapy for Cutaneous Leishmaniasis and Post Kala-Azar Dermal Leishmaniasis** (COLLABORATIVE + \$POOL + PUSH & DELINK) was a CWEG proposal from the U.S. FDA and Osaka University.¹⁴²

PDPs working across diseases

Development for Easy to Use and Affordable Biomarkers (COLLABORATIVE + ACCESS LICENSES), a CWEG proposal, is focused on the use of a high-throughput biomarker screening platform for diagnostic development focused on NTDs. The project would screen biomarkers for four different parasitic diseases, develop and optimize field deployable tests, and see regulatory approval and ultimate use of the resulting diagnostics in endemic areas. Resulting IP will rest with whoever owns it, but the project would seek non-exclusive licenses to facilitate access in developing countries.¹⁴³

Multiplexed Point-of-Care Test for Acute Febrile Illness (COLLABORATIVE + OPEN & DELINK), a CWEG proposal, plans to create a consortium to develop a multiplexed point-of-care test for at least 5-6 acute febrile illnesses via an open lateral flow platform. One of the goals of the project is to delink the cost of R&D from monopolies on final products. Governments might be encouraged to make advance market commitments.¹⁴⁴

x. Initiatives addressing 4 or more innovative R&D mechanisms

The **MSF 3P Project** (COLLABORATIVE + PUSH + PULL + IP/POOL + DELINK), a CEWG proposal, proposed an open collaborative platform with pooling of IP and use of both push and pull financing mechanisms to foster development of new proven treatment regimens for TB, and particularly MDR-TB. The 3P Project proposal offers benefits over the current TB drug R&D framework by: reducing duplication of research



efforts, thereby saving time and money; reducing the risks associated with developing potential combinations early in the R&D process; accelerating the development of all-new drug regimens; reducing the risk of resistance to new compounds by ensuring their use as part of regimens; coordinating disparate sources of funding and linking financial rewards to an obligation to share scientific and clinical data and IPR; separating ('delinking') R&D costs from the final price of the new TB combination regimen.¹⁴⁵ This proposal has been critiqued as needing further development and identified sources of funding.

The Visceral Leishmaniasis Global R&D & Access Initiative (COLLABORATIVE + PUSH + PULL + \$POOL + DELINK) is an accepted CWEG pilot project creation of a coordinated and collaborative Visceral Leishmaniasis Initiative focused on financing R&D with development of diagnostics and chemotherapies as primary objectives. It would combine existing groups and initiatives into a single organization, with de-linkage of R&D from product pricing as a primary objective.¹⁴⁶

Antibiotics Innovation Funding Mechanism (POOL + PUSH + PULL + OPEN + DELINK), a CWEG proposal, would have the following features: creation of new financial innovation incentives that are delinked from drug prices; elimination of perverse incentives for drug developers to promote inappropriate or low value use of drugs and to conserve antibiotic resources; creation of economic incentives for open sharing of knowledge, data, materials, and technology; competitive production of generic supplies of products at affordable prices; transfer of technology to drug manufacturers in developing countries, and sustainable financing for open source development of new antibiotics from a tax on product sales.¹⁴⁷

Additional Initiatives addressing 4 or more innovative R&D mechanisms

- **The Open Source Multiplex POC Fever Diagnostic Project** (COLLABORATIVE + PUSH + PULL + OPEN + DELINK), a CWEG proposals, proposing the creation of a new ecosystem for financing the development of an open source, multiplex, point of care (POC) diagnostic test via push and pull incentive-based mechanisms.¹⁴⁸
- **ANDI as the Regional Coordination Mechanism for Demonstration Projects and Product R&D in Africa** (COLLABORATIVE + POOL + PUSH + OPEN + DELINK), a CWEG proposal, would leverage the existing ANDI structure and create an innovation hub to pool funds and provide grants in order to develop and promote access to medicines, diagnostic tests, medical devices, and other technologies primarily for type II and III diseases. It would focus on traditional medicines and natural products.¹⁴⁹



- **Combatting Tuberculosis in the Region by Development of Diagnostics and Drugs** (COLLABORATIVE + OPEN + PUSH + PULL + POOL + DELINK), a CWEG proposal focused on the creation of an open and collaborative platform for development of TB diagnostics and drugs with pooling of resources and push and pull incentives implemented.¹⁵⁰

xi. Research and Development Treaty or Agreement

An Essential Health and Biomedical R&D Treaty (\$POOL + OPEN + DELINK), a CEWG proposal and recommendation of the CEWG final report, proposes the adoption of a binding international treaty for countries to share the costs of medical R&D on a fair-share basis.¹⁵¹ The form of the resulting “contribution” could be quite varied, but adoption of the treaty would allow radical delinking of the pooled costs of R&D/innovation from the price of resulting medical technologies. However, instead of only a few countries contributing to the costs of R&D, costs would be shared on a transparent and sustainable basis. The treaty foresees the creation of participatory coordination mechanisms and some efforts to prioritize and guide research efforts. The treaty proposal has been seriously considered at the WHO, but it has also been critiqued. In part, its proposals with respect to existing IP regimes is unclear, though it did initially propose freedom from trade-related enforcement actions for countries acceding to the proposed treaty and fulfilling their commitments. In addition, to the extent it proposes a central R&D prioritization and coordination platform, it risks undermining the complex systems by which innovation is best accomplished.¹⁵² This proposal has already gone through substantial evolution over the past five years. It has generated both strong interest and deep skepticism.

Conclusion

Taken as a whole, there has been a significant array of recent efforts to chip away at some of the innovation dilemmas and gaps, particularly with respect to priority infectious and neglected diseases. But larger embarkation focused on a substantial reworking of the incentive systems for medical innovation while ensuring universal access have not been undertaken. Similarly, past efforts have principally focused on low- and middle-income countries, and neglected the growing crisis of affordability in high-income countries as well. Likewise, although there have been many past critiques of the TRIPS Agreement and of national IP regimes and their impacts on access to medicines, few radical proposals for dismantling or significantly modifying the current system of exclusive rights for medical inventions have been considered.



This brief background paper cannot and does not do justice to the myriad analyses, initiatives, and proposals undertaken to try to address certain dysfunctionalities, incoherencies, market failures, inefficiencies, and inequities in the current global regime for incentivizing needed innovation and achieving equitable access to new, quality assured medical technologies. Innovators must be supported and rewarded and the human right of access to the benefits of scientific advance and to health and life itself must also be ensured. For the High-Level Panel to review the entire array of past thinking and experience to date would be an enormous undertaking, but to neglect the contours of past efforts might undermine deliberations. Nonetheless, the task of the High-Level Panel is not to duplicate these past efforts but to be informed by them – their successes and limitations – and to consider new territory and new, perhaps more far-reaching and sustainable solutions.

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- ⁷⁹ See *Longitude Prize Open*, <https://longitudeprize.org/>. See UAEM at p. 35.
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- ⁹⁰ See *The Bridging Interventional Development Gaps Programme* <https://ncats.nih.gov/bridgs>. UAEM at pp. 53-54.
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- ¹¹⁹ This portion of the survey includes proposals submitted to the WHO CWEG process described in Part 1 of this Background Paper.
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- ¹²⁷ See The Health Impact Fund, <http://healthimpactfund.org/>. UAEM at pp. 134-35.
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