Report of the UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

Promoting innovation and access to health technologies

September 2016

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

This is an independent report prepared by the High-Level Panel on Access to Health Technologies, convened by the United Nations Secretary-General in November 2015. The opinions expressed in this report are the authors' own and do not necessarily reflect the views of the UN Secretary-General, the Executive Office of the United Nations Secretary-General or the United Nations.

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PREFACE

Never in the past has our knowledge of science been so profound and the possibilities to treat all manner of diseases so great. Many sources of transmissible and non-transmissible diseases have been identified, and therefore prevention, including the fight against bacteria, viruses and parasites, has improved dramatically. New generations of medicines and their combinations are treating patients whose prognosis some years ago would have been fatal. The development of medical devices, the ability to combine new materials and use micro- and even nanotechnology and computer science are increasing the safety of interventions and replacing natural functionalities. Progress in fundamental research is nourishing an exceptional phase of development of medicines, vaccines, diagnostics and medical devices.

And yet, many people and communities in need of effective prevention methods, life-enhancing and life-saving treatments and rehabilitation do not receive them. In some cases, populations live in such unhealthy environments that they remain at daily risk of becoming or staying ill. Or, their health services are not accessible or so poorly organized and equipped that they cannot deliver what is necessary. In other cases, vaccines, diagnostics and medicines have not yet been developed for defeating the diseases from which they suffer. Many face prices that are too high, either for those who are paying out-of-pocket or for health systems at risk of rationing treatments. Availability, affordability and adaptation to specific settings and patient categories remain problematic in many regions and for many populations throughout the world. Meanwhile, new threats – new diseases and drug-resistant diseases – are emerging, for which global solutions must be found urgently.

In short, on one hand we are witnessing the immense potential of science and technology to advance medicine and healthcare, while on the other hand we are severely challenged by gaps and failures in addressing disease burdens and emerging diseases in many countries and communities.

On 19 November 2015, United Nations Secretary-General Ban Ki-moon announced the creation of a High-Level Panel on Innovation and Access to Health Technologies (the 'High-Level Panel for short). In outlining our mandate, the Secretary-General called upon us to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."

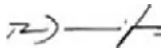
In line with the goals of United Nations Member States as articulated in the 2030 Agenda for Sustainable Development, and in particular in support of attaining Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages," the scope of the High-Level Panel's mandate was simultaneously ambitious and limited. It was limited because we were not assigned the task of analysing all the reasons why health technologies are not available or affordable, even if we were always conscious of the many unmet obligations with regard to the right to health. It was ambitious because we aimed to propose real solutions that would help promote research, development, innovation and could increase access to medicines, vaccines, diagnostics and medical devices.

Building on positive initiatives developed in collaboration with public and private partners during the last decades, recognizing the importance of mitigating trade rules and public health obligations (as did the World Trade Organization when adopting an agreement on trade-related aspects of intellectual property and the Doha Declaration), aware of the necessity to build coherence and accountability both nationally and internationally in the achievement of public health objectives, we hope to have contributed to further positive change in innovation and access to health technologies.

The High-Level Panel came together as a diverse groups of individuals from various backgrounds, experiences and continents. Discussions took place in an atmosphere of mutual respect, with each of us recognizing that the world community as a whole, and each one of us, shares a stake in this subject matter, and that we can and must do better. Even if members of the High-Level Panel did not agree on every detail of the report, we reached broad consensus on most aspects. And most importantly we are unanimous on the need to act, and to act now.

Members of the High-Level Panel were far from alone in their endeavours. Our deliberations were informed by and benefited from a broad consultative process, which included a generous response to a public call for contributions that netted 182 submissions, many of which were of a high quality. Hearings and Global Dialogues were held in London and Johannesburg in March 2016 to examine the proposals and incorporate the views and inputs from concerned parties and affected communities. The High-Level Panel was ably supported by an Expert Advisory Group, under the dedicated chairmanship of Justice Michael Kirby. This group brought together the knowledge and experience of expertise from civil society, industry, academia and from many United Nations and multilateral organizations. The members of the High-Level Panel would like to extend their deepest gratitude to all contributors, whom we unreservedly acknowledge for enlivening and enriching our debates and strengthening the recommendations.

To the extent possible, we have grounded our recommendations in concrete and actionable steps. We hope the report may serve stakeholders – governments, policy-makers, business leaders, representatives of international organizations and civil society alike – as a useful point of reference and evidence to support a stepped up mobilization for improving health and well-being for all.



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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immune deficiency syndrome
AMR	Antimicrobial resistance
ARV	Antiretroviral
CAFTA-DR	Dominican Republic-Central America Free Trade Agreement
CESCR	United Nations Committee on Economic, Social and Cultural Rights
CEWG	Consultative Expert Working Group on Research and Development: Financing and Coordination (WHO)
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health (WHO)
DNDi	Drugs for Neglected Diseases initiative
EID	Emerging infectious disease
EML	Essential Medicines List
EPA	Economic Partnership Agreement
FDA	Food and Drug Administration (United States)
FTA	Free trade agreement
GAP-AMR	Global Action Plan on Antimicrobial Resistance (WHO)
GARD	Global Antibiotic Research and Development Partnership (WHO-DNDi)
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism (WHO)
HIV	Human immunodeficiency virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICTRP	International Clinical Trials Registry Platform
ICTSD	International Centre for Trade and Sustainable Development
INN	International non-proprietary name
IP	Intellectual property
LDC	Least developed country
MDG	Millennium Development Goal
MDR-TB	Multi-drug-resistant tuberculosis
MPP	Medicines Patent Pool
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organization
NIH	National Institutes of Health (United States)
NTD	Neglected tropical disease
OECD	Organization for Economic Co-operation and Development
OHCHR	Office of the United Nations High Commissioner for Human Rights
PDP	Product development partnership
PEPFAR	United States President's Emergency Plan for AIDS Relief
R&D	Research and development
SDG	Sustainable Development Goal
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases (UNICEF, UNDP, World Bank, WHO)
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
V3P	Vaccine Product, Price and Procurement web platform (WHO)
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

GLOSSARY[1]

Bayh-Dole Act: U.S. legislation enacted in 1980, which created a uniform federal policy allowing universities and research institutions to elect to retain title, through patent protections, to inventions created in whole or in part from federal funding.

Biologic: Any virus, therapeutic serum, toxin, antitoxin, hormone or protein, including monoclonal antibodies or similar products used to diagnose, prevent, treat or cure a disease or condition.

Biomedical: The field of science, industry and research that applies the natural sciences, especially the biological and physiological sciences, to clinical medicine to better understand disease processes and develop therapies for the prevention and treatment of diseases and conditions that cause illness.

Biosimilar: A biologic product sufficiently similar in quality, safety and efficacy to an already licensed and market-approved biologic product that is shown to have no clinically meaningful differences from the original biologic product.

Biotechnology: The use of biological processes, organisms or systems to manufacture treatments intended to improve the quality of human life. Biotechnology is an interdisciplinary science-based technology that combines knowledge from various fields, such as microbiology, biochemistry, genetics, process technology and chemical engineering.

Bolar exemption: A legal exception that permits the use of a patented invention before the patent expires for the purposes of obtaining marketing approval of a generic product for commercialization once the patent expires.

Clinical trial: A research study in which candidate therapies are tested on human subjects to identify their clinical, pharmacological or other effects, adverse reactions and absorption, distribution, metabolism and excretion in the human body in order to ascertain their safety and efficacy. There are four phases of clinical trials: Phase I (a candidate therapy is given to a small group of people for the first time); Phase II (the candidate therapy is given to a larger group of people to further evaluate its safety and efficacy); Phase III (the candidate therapy is given to larger groups of people to confirm its efficacy, monitor side effects, compare it to commonly used treatments and collect safety information); and Phase IV (post-marketing studies gather information on the health technology's efficacy in various populations and a side-effect associated with long-term use).

Data exclusivity: A legal regime in which, for a specified period of time, national regulatory authorities are barred from the use of clinical studies and data developed by an originator company to register the generic equivalent of a medicine. Generic manufacturers seeking regulatory approval within a period of data exclusivity must conduct new clinical trials to prove the safety and efficacy of their equivalent products.

Delinkage: A term used to describe a key characteristic of any financing model of innovation characterized by the uncoupling of R&D costs and consumer prices for health technologies. Examples of delinkage models include grants, prizes and advance market commitments, among others.

Doha Declaration on the TRIPS Agreement and Public Health: The World Trade Organization (WTO) Declaration on the TRIPS Agreement and Public Health (2001), which affirmed, inter alia, that the TRIPS 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."

Evergreening: A term used to describe patenting or marketing strategies to extend the period of patent protection or effective period of market exclusivity, which are considered to be unjustifiable and therefore abusive. In some cases, for example, this might involve the filing of multiple, often successive, patent applications on minor and insignificant variants or indications of the same compound

Health technology: Medicines, vaccines, diagnostics and medical devices used to prevent, diagnose and treat health problems.

Neglected diseases: Diseases for which there is a lack of sufficient medical innovation, resulting in inadequate, ineffective or non-existent means to prevent, diagnose and treat them. The lack of sufficient medical innovation is often rooted in an absence of market incentives owing to the low purchasing power of the populations disproportionately affected by such conditions.

Originator: A term that generally refers to the product that was first authorized worldwide for marketing (normally as a patented product). The term also refers to the company that commercialized the originator product.

Orphan disease: A disease that affects only small numbers of individuals. The threshold number varies from country to country. An orphan disease may affect fewer than 200,000 individuals (United States), fewer than 50,000 (Japan) or less than 2,000 (Australia). Definitions vary from diseases affecting about 1 to 8 in 10,000 individuals.

Paragraph 6 decision: An agreement reached by WTO Members on 30 August 2003 in response to paragraph 6 of the Doha Declaration. The paragraph 6 decision grants waivers of the TRIPS Agreement Article 31(f) and (h) to permit the manufacture of pharmaceutical products under a compulsory licence within the territory of a WTO Member predominantly for export to another WTO Member that lacks the requisite domestic manufacturing capacity. With this solution, subject to a number of conditions, the predominant or total consignment of pharmaceutical products manufactured under compulsory licence may be exported to another country.

[1]The definitions in this glossary are not designed to provide a technical description of every aspect of national and international legal provisions where these are applicable. Rather, the glossary was developed as a general guide for non-technical readers for terms used in the report.

Patent: A statutory, time-limited exclusive right granted by a national authority to prevent others from legally making, using, offering for sale or selling a qualifying invention.

Patentability criteria: Requirements that must be satisfied before a patent is awarded. These are (1) subject matter for eligibility, (2) novelty, (3) an inventive step and (4) industrial application. The precise nature of these requirements is not defined in the TRIPS Agreement and it is up to countries to define these in their laws and policies.

Patent pools: An agreement among patent holders to voluntarily license a set of their patents to one another or to third parties. Patent pools are often administered or managed by institutional frameworks to facilitate the negotiation of such agreements.

Publicly-funded research: For the purposes of this report, this refers to research that is primarily or totally financed by government funds and disseminated through government bodies as well as academic and research institutions.

Test data protection: A legal obligation imposed by the TRIPS Agreement on WTO Members to protect undisclosed test data from unfair commercial use. Such data is required to be submitted as a condition of approving the marketing of a pharmaceutical or agricultural chemical product. (Contrast to data exclusivity above).

TRIPS: The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

TRIPS flexibilities: A term used broadly to describe a set of norms, rules and standards that allow variations in the implementation of the TRIPS Agreement obligations, including limits on the exercise of intellectual property rights.

Voluntary licence: A licence granted by a patent holder to a third party to produce and/or market and distribute a patented product, usually in exchange for a royalty on net sales and certain other conditions (for example, geographical restrictions on where the product can be sold).

WHO Essential Medicines List: The World Health Organization (WHO) Essential Medicines List (EML) contains therapeutic medicines that satisfy the priority healthcare needs of the global population. Medicines are deemed 'essential' by WHO following an evaluation of disease prevalence, public health relevance, evidence of clinical efficacy and safety and comparative costs and cost-effectiveness. The WHO EML is often used as a guide in the development of national essential medicines lists.

EXECUTIVE SUMMARY

In September 2015, 193 Member States of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) 3 that aims to ensure healthy lives and promote the well-being of all people of all ages. SDG 3 is an important vehicle for realizing the right to health and the right to share in the benefits of scientific advancements, whose affirmation dates back to the Charter of the United Nations (1945), the Universal Declaration of Human Rights (1948) and the Constitution of the World Health Organization (WHO) (1948). These rights are also enshrined in the International Covenant on Economic, Social and Cultural Rights (1966) and various other international treaties, declarations and national laws, including at least 115 constitutions.

Consistent with the vision of the 2030 Agenda and a recommendation by the Global Commission on HIV and the Law that the United Nations Secretary-General establish a high-level body to propose ways of incentivizing health technology innovation and increasing access to medicines and treatment, Secretary-General Ban Ki-moon, in November 2015, announced the appointment of a High-Level Panel on Innovation and Access to Health Technologies.

In keeping with the commitment of United Nations Member States to enhance policy coherence for sustainable development, the High-Level Panel's terms of reference called for it to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies," among other things. In accordance with the principle of universality that underpins the 2030 Agenda and its aspiration to leave no one behind, the High-Level Panel views innovation and access to health technologies as a multi-dimensional and global problem that affects all countries.

Health technology innovation and access

Over the last few decades, medical innovation has dramatically improved the lives of millions of people across the globe. Vaccines have significantly reduced the prevalence of diseases, ranging from polio to human papillomavirus. Antiretroviral medicines have greatly improved the lives of people living with the Human Immunodeficiency Virus (HIV). Personalized strategies based on molecularly-targeted medicines are likely to become central to cancer treatment in the future. Despite this noteworthy progress, millions of people continue to suffer and die from treatable conditions because of a lack of access to health technologies.

Investment in research and development (R&D) of health technologies does not adequately address a number of important health needs. In some cases, the cause lies in inadequate resourcing of R&D for diseases where the market does not provide sufficient return on investment. Antibiotics typically offer little pecuniary reward for years of often costly research. In these circumstances, experts warn that drug-resistant viruses, bacteria, parasites and fungi could cause 10 million deaths a year worldwide by 2050. The current model of medical innovation is ill-equipped to respond to the increasing emergence of infectious diseases, such as Ebola and Zika. Meanwhile, neglected tropical diseases (NTDs) continue to receive inadequate funding for R&D and access to health technologies, despite more than a billion people living with one or more NTD. The situation is driven by the relatively low purchasing power of people disproportionately affected by such conditions.

There are many reasons why people do not get the healthcare they need, including, inter alia, under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, regulatory barriers, poor health education, unavailability of health insurance, exclusion, stigma, discrimination and exclusive marketing rights. The High-Level Panel acknowledges the importance of addressing these multiple determinants to health technology innovation and access. However, the High-Level Panel's mandate is focused on one aspect of a complex challenge: the incoherencies between international human rights, trade, intellectual property (IP) rights and public health objectives.

Policies and agreements related to human rights, trade, intellectual property rights and public health were developed with different objectives at different times. State obligations include duties not only to respect, but to protect and fulfil the right to health. This requires taking proactive measures to promote public health. As reaffirmed by a recent Human Rights Council resolution, ensuring access to medicines, and particularly to essential medicines, is a fundamental element of these obligations. Trade rules and intellectual property laws were developed to promote economic growth and incentivize innovation. On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives of World Trade Organization (WTO) Members.

The adoption of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994 ushered in a new and unprecedented era of global intellectual property norms and created a new standard of intellectual property protection and enforcement. However, negotiators included safeguards, or 'flexibilities,' within the TRIPS Agreement that could be used by signatories to tailor national intellectual property regimes so that countries could fulfil their human rights and public health obligations (for instance, laws and regulations regarding competition, government procurement and medicines). The proliferation of free trade agreements containing expansive patent and test data protections on health technologies, which exceed the minimum standards for intellectual property protection required by the TRIPS Agreement (so-called 'TRIPS-plus' provisions), may impede access to health technologies. Also, an uneven application of health and trade policy within and among states can create tensions that fuel policy incoherence.

Intellectual property laws and access to health technologies

Public health-sensitive intellectual property rules and mechanisms can help address the misalignment between profit-driven innovation models and public health priorities. Voluntary licences, entered into between right holders and third parties to facilitate the market entry of more affordable health technologies, have helped to lower treatment costs in many countries. TRIPS flexibilities – for example, the freedom to determine patentability criteria and further define concepts such as "novelty," "inventive step" and "industrial applicability" – can ensure that patents are only awarded for genuine innovation. Similarly, the ability to determine the terms upon which compulsory licences are issued allows governments to fulfil their human rights obligations by securing the availability and affordability of health technologies. Many governments have not used the flexibilities available under the TRIPS Agreement for various reasons ranging from capacity constraints to undue political and economic pressure from states and corporations, both express and implied. Political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violates the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement, as reaffirmed by the Doha Declaration. This pressure undermines the efforts of states to meet their human rights and public health obligations. The use of TRIPS flexibilities may also be impeded by the proliferation of bilateral and regional free trade agreements containing TRIPS-plus provisions.

The policies of public funders of health technology R&D can also play an important role in enhancing health technology innovation and access. The United States, for instance, holds a central position in health technology innovation. The country's R&D and access policies influence other actors, including private and public sector donors and foundations, and have an impact on access to the fruits of technology worldwide. The introduction of the 1980 Bayh-Dole Act in the United States significantly changed academic research by allowing universities and public research institutions to patent the results of federally-funded research and license private enterprises to develop them. However, limiting access to academic discoveries can obstruct follow-on innovation and force taxpayers to pay twice for the benefits of publicly-funded research. Strong, enforceable policies on data sharing and data access should be a condition of public grants. Public funding agencies should strongly encourage patenting and licensing practices that benefit public health, including the use of non-exclusive licences, the donation of intellectual property rights, participation in public sector patent pools and other mechanisms that maximize innovation while promoting access. Open models of innovation can also lower entry hurdles and accelerate the pace of development of health technologies, including those needed to combat emerging infectious diseases.

New incentives for research and development of health technologies

Market-driven R&D has been credited by some for producing a number of important health technologies that have improved health outcomes significantly worldwide. However, significant gaps in health technology innovation and access persist. Under the prevailing model, the biomedical industry, with the help of intellectual property and data protections, in addition to benefiting from public funding for research, recoups the costs of its R&D and marketing through high product prices protected by patent monopolies and data and market exclusivities. As a result, new technologies are rarely developed for health conditions which cannot deliver high returns, such as bacterial infections that only require antibiotics. Rare diseases that affect comparatively small proportions of the population have not traditionally attracted investments although this is changing.

Various efforts are being undertaken by governments, philanthropic organizations, international entities, civil society groups and the private sector to resolve the incoherence between market-driven approaches and public health needs. However, such efforts tend to be fragmented, disparate and insufficient to deal with priority health needs on a sustainable, long-term basis. A much greater effort must be directed to supplementing the existing market-driven system by investing in new mechanisms that delink the costs of R&D from the end prices of health technologies.

Identification of global health priorities is necessary to efficiently distribute scarce health resources, to substantially improve the health status of populations and to enhance global preparedness for future health crises. The current patchwork of public, private and philanthropic funding cannot sufficiently and sustainably improve access to health technologies. Greater and more sustainable financial commitments are needed from both the public and private sectors and should be coordinated to achieve maximum utility and effect.

Governance, accountability and transparency

Good governance, strong and concrete accountability mechanisms and greater transparency are decisive enablers of the 2030 Agenda. An important factor behind the incoherence between human rights, trade, intellectual property and public health lies in the diverse accountability mechanisms and transparency levels of these different, but overlapping spheres. Trade- and intellectual property-related accountability mechanisms are typically regulated by the WTO Dispute Settlement Understanding and dispute settlement provisions found in free trade and investment agreements. In contrast, human rights and public health accountability mechanisms are characterized by varying and often limited degrees of precision, legal weight and enforceability.

Transparency is necessary to hold governments, the private sector and other stakeholders accountable for the impact of their actions on access to health technologies. However, accurate and comprehensive information on the costs of R&D, marketing, production and distribution, as well as the end prices of health technologies, can be difficult to aggregate. Existing public databases of health technology prices managed by international organizations and civil society groups, while laudable, tend to be limited in scope and accuracy, in part because of discounts, mark-ups, taxes and regional pricing differences. The absence of transparency in clinical trial data and a lack of coordination within national drug regulatory authorities can contribute to delays in the registration of new health technologies. Procurement decisions and generic manufacturing are often delayed by the absence of clear, accurate and up-to-date information on existing and expired patents. Moreover, trade and investment agreements containing TRIPS-plus provisions are often negotiated in secret. This lack of transparency makes it difficult to hold governments and other stakeholders accountable for the impact of their policies and actions on innovation and access to health technologies.

The incoherencies between the right to health, trade, intellectual property and public health objectives can only be resolved using robust and effective accountability frameworks that hold all stakeholders responsible for the impact of their decisions and actions on innovation and access to health technologies.

Recommendations

Intellectual property laws and access to health technologies

World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. More specifically:

TRIPS flexibilities and TRIPS-plus provisions

World Trade Organization (WTO) Members must make full use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities as confirmed by the Doha Declaration to promote access to health technologies when necessary.

WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that are in the best interests of the public health of the country and its inhabitants. This includes amending laws to curtail the evergreening of patents and awarding patents only when genuine innovation has occurred.

The United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should cooperate with one another and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.

These multilateral organizations should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.

WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be reported to by the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure which includes taking punitive measures against offending WTO Members.

Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.

Publicly-funded research

Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research.

Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices. Such practices

may include publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others. Sufficient incentives must be in place in these practices to make it attractive for developers to underwrite the cost of bringing a product to market at affordable prices that ensure broad availability.

Universities and research institutions that receive public funding should adopt policies and approaches that catalyse innovation and create flexible models of collaboration that advance biomedical research and generate knowledge for the benefit of the public.

New incentives for research and development of health technologies

It is imperative that governments increase their current levels of investment in health technology innovation to address unmet needs.

Stakeholders, including governments, the biomedical industry, institutional funders of healthcare and civil society, should test and implement new and additional models for financing and rewarding public health research and development (R&D), such as the transaction taxes and other innovative financing mechanisms.

Building on current discussions at the WHO, the United Nations Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all. The Convention should focus on public health needs, including but not limited to, innovation for neglected tropical diseases and antimicrobial resistance and must complement existing mechanisms.

As a preparatory step, governments should form a Working Group to begin negotiating a Code of Principles for Biomedical R&D. The principles would apply to public R&D funds and should also be adopted by private and philanthropic funders, product development partnerships, universities, the biomedical industry and other stakeholders. Governments should report annually on their progress in negotiating and implementing a Code of Principles as a preparatory step to negotiating the Convention in the United Nations General Assembly.

Governance, accountability and transparency

Governments

Governments must review the situation of access to health technologies in their countries in light of human rights principles and States' obligations to fulfil them, with assistance from the Office of the United Nations High Commissioner for Human Rights (OHCHR) and other relevant United Nations entities. The results of these assessments should be made publicly available. Civil society should be financially supported to submit their own shadow reports on innovation and access to health technologies. Such national reviews should be repeated at regular intervals.

Governments should strengthen national level policy and institutional coherence between trade and intellectual property, the right to health and public health objectives by establishing national inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access. Appropriate member/s of the national executive who can manage competing priorities, mandates and interests should convene such bodies. The deliberations and decisions of such groups should operate with a maximum of transparency. Civil society should be financially supported to participate and submit their shadow reports on innovation and access to health technologies.

Multilateral organizations

The United Nations Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access. Challenges and progress on innovation and access to health technologies under the ambit of the 2030 Agenda, as well as progress made in implementing the recommendations of this High-Level Panel, should be monitored by this body. Membership should comprise of governments, representatives from United Nations and multilateral organizations, civil society, academia and the private sector.

The United Nations Secretary-General should establish an inter-agency taskforce on health technology innovation and access. This taskforce, operating for the duration of the SDGs, should work toward increasing coherence among United Nations entities and relevant multilateral organizations like the WTO. The taskforce, charged with overseeing the implementation of the High-Level Panel's recommendations should be coordinated by the United Nations Development Group and report annually to the United Nations Secretary-General on progress made in enhancing United Nations system-wide coherence on innovation and access to health technologies.

The United Nations General Assembly should convene a Special Session, no later than 2018, on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access as set out in the 2030 Agenda. Civil society should be financially supported to participate and submit their reports on innovation and access to health technologies at this Special Session.

Private sector companies

Biomedical private sector companies involved in health technology innovation and access should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.

Private sector companies should have a publicly available policy on their contribution to improving access to health technologies setting out general and specific objectives, timeframes, reporting procedures and lines of accountability and a governance system that includes direct board-level responsibility and accountability on improving access to health technologies.

R&D, production, pricing and distribution of health technologies

Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to: (1) the costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and (2) any public funding received in the development of the health technology, including tax credits, subsidies and grants.

Building on the Global Price Reporting Mechanism (GPRM), V3P and others, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.

Clinical trials

Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the WHO Clinical Trials Registry Platform, clinical trials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.

To facilitate open collaboration, reconstruction and reinvestigation of failures, governments should require that study designs and protocols, data sets, test results and anonymity-protected patient data be available to the public in a timely and accessible fashion. Those undertaking clinical trials must not prevent researchers from publishing their findings.

Patent information

Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include: (1) standard international common names for biological products; (2) international non-proprietary names for products, either as known at the time of application or after the granting of a patent; and (3) dates of grant and expiry.

INTRODUCTION

In September 2015, 193 Member States of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) 3 that aims to ensure healthy lives and to promote the well-being of all people of all ages. SDG 3 comes with specific targets for supporting research, development and access to essential medicines and vaccines.[1] The 2030 Agenda also reinforces the importance of human rights, including the right to health and the right to share in the benefits of scientific advancements, whose affirmation dates back to the Charter of the United Nations (1945),[2] the Universal Declaration of Human Rights (1948)[3] and the World Health Organization (WHO) Constitution (1948).[4] These rights are also found in numerous global and regional treaties and in many national constitutions.[5] [6] Despite the presence of these rights and the commitment of countries to advance public health objectives, millions of people do not have access to the health technologies that form a core component of the right to health. The reasons for this are complex and numerous. The United Nations Secretary-General released a synthesis report in 2015 identifying some of the underlying causes. One of the main causes cited in the report was incoherence between current modes of international governance in trade, finance and investment on the one hand and norms and standards for labour, the environment, human rights, equality and sustainability on the other.[7] This report called for steps to be taken to ensure that "global intellectual property regimes and the application of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are fully consistent with and contribute to the goals of sustainable development." [8]

Consistent with the vision of the 2030 Agenda, including a commitment by United Nations Member States to enhance policy coherence for sustainable development and a recommendation by the Global Commission on HIV and the Law that the United Nations Secretary-General establish a high-level body to propose ways of incentivizing health technology innovation and increasing access to treatment,[9] Secretary-General Ban Ki-moon, in November 2015, announced the appointment of a High-Level Panel on health technology innovation and access, or for short, the 'High-Level Panel on Access to Medicines' (the High-Level Panel). The High-Level Panel was comprised of 15 eminent individuals with an understanding of a broad range of legal, commercial, trade, public health and human rights issues central to promoting innovation and access to health technologies. Their work was supported by a 25-member Expert Advisory Group constituted from academia, the private sector, civil society and relevant United Nations and international organizations, such as the World Trade Organization (WTO).

The High-Level Panel builds on previous and existing work in the field of health technology innovation and access. These include developments at WHO, the Human Rights Council and the United Nations General Assembly since the release of the report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). These initiatives have guided governments when addressing the important challenges related to health technology innovation and access to prevent and treat various infectious and noncommunicable diseases.

The High-Level Panel's mandate includes a request by the United Nations Secretary-General to: *"Review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."* [10]

In accordance with the principle of universality that underpins the 2030 Agenda and its aspiration to leave no one behind,[11] the High-Level Panel views access to medicines, vaccines, diagnostics and related health technologies as a serious, multi-dimensional global problem, with challenges that affect all people and all countries. Adopting a broad approach is necessary at this juncture in history, as the High-Level Panel recognizes that the costs of health technologies are rising globally and are being felt by individuals and by public and private insurance schemes in both wealthy and resource-constrained countries alike. These rising costs have the potential to push more people into poverty. With populations living longer, the need for health technologies, especially for noncommunicable diseases, only grows, placing a strain on budgets to meet greater healthcare burdens—not to mention the health-related threats of a global nature, such as increasing incidences of resistance to antibiotics and emerging transmissible diseases.

The report is structured in four chapters:

- **Chapter one** ***(Health Technology Innovation and Access)*** examines the problem at the heart of the High-Level Panel's mandate: asymmetries of power between institutions and the incoherencies in law, policy and practice between the right to health, international trade and intellectual property rules and public health objectives and their effect on health technology innovation and access.

- **Chapter two** ***(Intellectual Property Laws and Access to Health Technologies)*** discusses the prevalent international intellectual property regime, the flexibilities contained therein that can be used to promote access to health technologies and examines why flexibilities have not been systematically used, as well as developments such as free trade agreements that may impede the use of TRIPS flexibilities.

- **Chapter three** ***(New Incentives for Research and Development of Health Technologies)*** highlights the role that increased coordination, priority setting and R&D can play in systematically addressing unmet health needs and examines some of the new models that can be used by various actors.

- **Chapter four** ***(Governance, Accountability and Transparency)*** examines governance and accountability mechanisms needed to promote health technology innovation and access, including the roles of key stakeholders. It highlights the need for transparency in the various stages of health technology innovation and access in order to strengthen coherence at all levels of policies and actions.

1. HEALTH TECHNOLOGY INNOVATION AND ACCESS

The last half-century has borne witness to a fertile period of medical innovation that has improved the health and lives of millions. During this time, a successful polio vaccine was developed and contributed to a 99% reduction in cases worldwide.[12] In 1996 triple-drug anti-retroviral (ARV) therapy was recommended, transforming the Acquired Immune Deficiency Syndrome (AIDS) from a death sentence to a manageable chronic disease.[13] Investments by industry, generic competition and collaborations between industry, philanthropy, governments, non-governmental organizations (NGOs) and the tenacious advocacy by patients and their allies have resulted in 17 million people accessing life-saving HIV treatments.[14] The introduction of a vaccine for rotavirus in 2006 has resulted in a dramatic reduction in deaths and hospitalizations of babies and young children.[15] The disfiguring, disabling mosquito-borne disease lymphatic filariasis (also known as elephantiasis), primarily endemic to Africa, can now be prevented with a single, annual, two-medicine treatment and medicines donated by manufacturers, delivered through mass administration programmes, have begun to slow infection and transmission in affected countries.[16] Scientists are developing breast cancer and lupus therapies based on discoveries in genetics,[17] as well as stem cell-based medicines.[18] Deadly and formerly incurable diseases are meeting their nemeses. Introduced in 2014, sofosbuvir, in combination with daclatasvir, cures almost all hepatitis C patients over a remarkably short period of time, with minimal side effects.[19] These advances, along with improvements in nutrition and sanitary conditions, have contributed to improved health outcomes across the world.

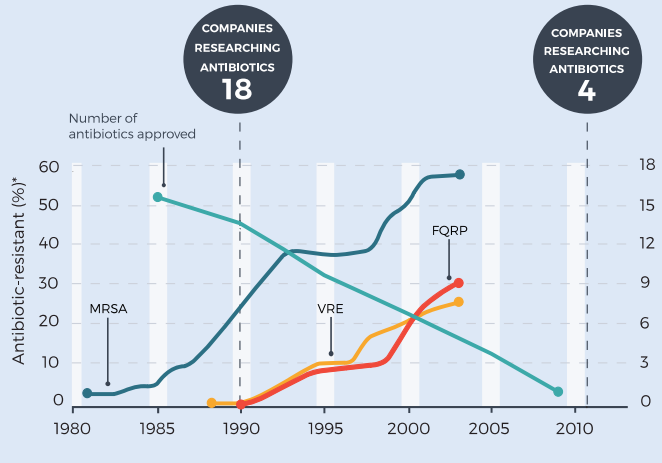
According to WHO, an estimated 1.7 billion people in 185 countries needed mass and/or individual treatment and care for neglected tropical diseases (NTDs) in 2014.[20] Despite NTDs accounting for approximately 12% of total disease burden, just 4% of therapeutic products registered between 2000 and 2011 were indicated for these diseases.[21] Rapid point-of-care diagnostics, particularly for use in resource-limited settings and in health emergencies, such as Ebola and Zika, are essential.[22] But diagnostics can be complex and costly to develop,[23] resulting in an inadequate number on the market.[24] And in spite of progress, paediatric formulations remain scarce for conditions that affect children.[25] The reasons behind the inadequate supply of paediatric formulations are complex and are also linked to a reluctance to conduct clinical trials with children.[26]

In spite of many notable advancements, numerous challenges remain. In some cases, progress has been uneven, leaving many people without access to the benefits of the advances made. The causes for this vary, but one can be attributed to inadequate investments in R&D for diseases for which the market does not provide sufficient financial return, as is the case for antimicrobial resistance (AMR). If not controlled or reversed, drug-resistant viruses, bacteria, parasites and fungi could, according to projections, cause 10 million deaths a year

Antimicrobial resistance (AMR) – a crisis in waiting

No more evident is the need for a collaborative global health response than with AMR, which threatens the foundation of modern health systems and can undermine efforts to achieve the SDGs.

As bacterial infections grow more resistant to antibiotics, companies are pulling out of antibiotics research and fewer new antibiotics are being approved.



*Proportion of clinical isolates that are resistant to antibiotic. **MRSA**, methicillin-resistant Staphylococcus aureus. **VRE**, vancomycin-resistant Enterococcus. **FQRP**, fluoroquinolone-resistant Pseudomonas aeruginosa.[1]

AMR estimated to kill more than **700,000** people globally per year today.[2]

If AMR is not addressed, **10 million** people are expected to die annually because of drug resistance by 2050.[2]

In the last **25 years** virtually no new antibiotics have been developed.[2]

The world can expect to lose about **100 trillion USD** worth of economic output by 2050 if antimicrobial drug resistance is not tackled.[3]

A continued rise in antimicrobial resistance would lead to a global reduction of **2% - 3.5%** in Gross Domestic Product (GDP) by 2050.[2]

[1] Cooper. A. *et al* (2011) Fix the antibiotics pipeline. Available at: http://www.readcube.com/articles/10.1038/472032a

[2] O'Neill, J. (2014) Antimicrobial resistance: Tackling a crisis for the health and wealth of nations. The review on antimicrobial resistance. Available at: http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

[3] WHO (2016) What you need to know about antibiotic resistance. Available at: http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

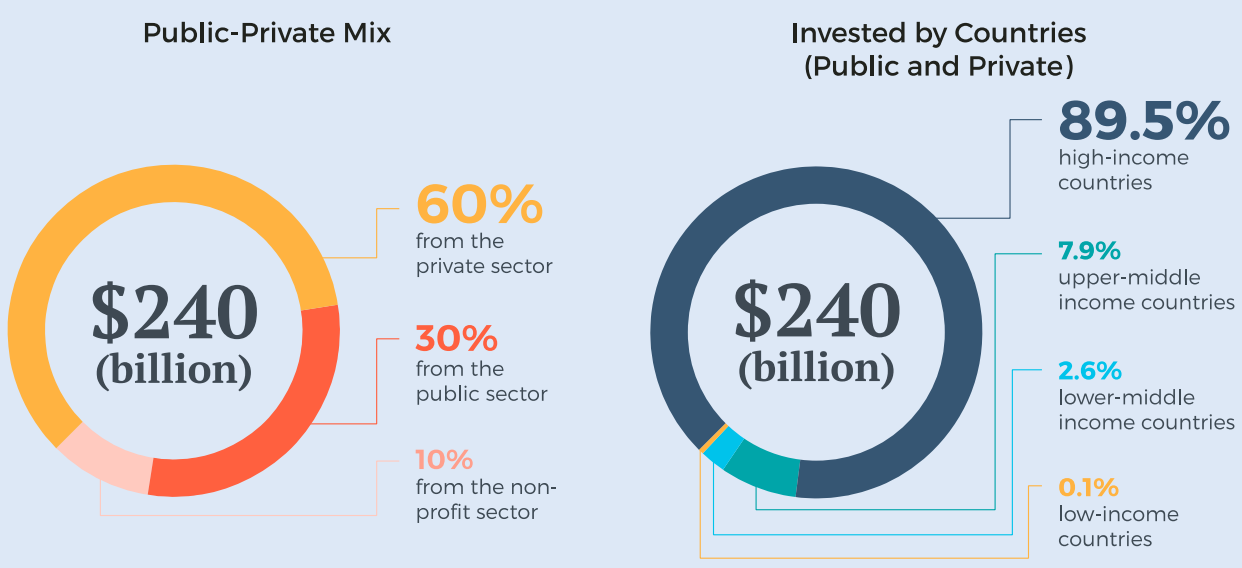
by 2050, and cost the global economy at least US$ 100 trillion, affecting wealthy and resource-constrained countries alike (see chart). Yet, aside from bedaquiline, a medicine approved in 2012 to treat multi-drug resistant tuberculosis (MDR-TB), only one novel class of antibiotics has been developed in the past 40 years. From a public health perspective, therefore, it is imperative to develop new antimicrobials and to control their use with the aim of preserving them, thereby breaking the resistance cycle. However, lower consumption signifies reduced sales, carving into any potential profit margins, such that few single players are willing to invest the financial, technical and human resources necessary to bring an antimicrobial medicine to market.

Coordinated and collaborative efforts of public-private partnerships and product development partnerships (PDPs) have been key to bringing together the resources and strengths of the private, philanthropic and public sectors to innovate and deliver several important health technologies.[27] International organizations, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), UNITAID and the United States President's Emergency Plan for AIDS Relief (PEPFAR), aggregate and distribute resources for tackling diseases, including malaria and tuberculosis, while the Gavi Alliance contributes to improving access to vaccines in poor countries. In the absence of a viable market, the existence of these mechanisms may help provide alternative incentives and financing for health technology innovation and access.[28] What some of these arrangements and mechanisms have in common is the concept of delinkage, which, for the purposes of this report, refers to separating the costs of R&D from the end prices of health technologies. Innovative mechanisms to address unmet needs have enabled policymakers to plan and budget R&D expenditure more rationally so as to use resources more efficiently and — most importantly — to invest according to public health priorities.[29]

Adequate investment in R&D by the public sector is crucial if governments are to fulfil their obligations with respect to the right to health. An analysis of spending on health technology R&D in wealthy countries found that 60% derived from the private sector and 40% from public and non-profit sources.[30] The percentages were reversed for R&D in diseases that heavily affect low- and middle-income countries, including HIV,[31] TB[32] and malaria.[33] For those conditions, the public sector provided approximately 60% of total R&D funding.

Innovation is vital to achieving the 2030 Agenda's goal of improving the health and well-being of all people at all ages and appears in a number of SDG targets. SDG 3 would require conducting more holistic situation assessments, prioritizing the most pressing public health needs by the funders of health R&D, financing equitably and sustainably and using public and private resources more prudently and strategically. Transparent, reliable and widely-available data is crucial to inform the policy-making process at various stages. This could include data on costs, pricing and patent information. It might also involve the creation or population of existing clinical trial

Investments in research and development (2009/2010)[1]



[1] Rounded estimates of total investment in health R&D in purchasing power parity-adjusted US$. See RØttingen, J., *et al.* (2013) Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?. The *Lancet*, 382(9900), pp.1286-1307.

data repositories, and easily accessible databases on patent and pricing by country and the costs of R&D. This information must be available for better governance and accountability and could help minimize redundancies and maximize returns on investments, ensuring innovation and access can take place that will benefit patients and public health objectives.

Cost is one of the key determinants of access, both in situations when patients pay out-of-pocket[34] and when governments are making choices about what to fund under national health and treatment programmes. According to WHO and the World Bank, 400 million people worldwide lack healthcare, including access to medicines, vaccines and diagnostics and medical devices.[35] Those who lack access are disproportionately poor, and three-quarters of them live in so called middle-income countries.[36] Individuals living on low incomes in many wealthy countries face challenges in accessing treatment for some infectious diseases, noncommunicable and rare diseases.[37] For example, a recent study found that the median nominal factory price of a 12-week course of sofosbuvir across 26 Organization for Economic Co-operation and Development (OECD) countries was US$ 42,017 and ranged from US$ 37,729 in Japan to US$ 64,680 in the United States. [38] These price discrepancies also reflect the capacity of countries to negotiate prices. Treatment for rare diseases can be exorbitantly costly. For instance, ivacaftor, an effective medicine for some people with cystic fibrosis, costs as much as US$ 294,000 per patient per year in wealthy countries (2011).[39]

Box 1: One South African patient's journey with extensively drug-resistant tuberculosis

South African Phumeza Tisile was diagnosed with TB in 2010. "First, I was diagnosed with 'normal TB,' then later I was told that I had multi-drug resistant TB, only to be told later again that I had extensively drug-resistant TB," explains Phumeza. The reason for the incorrect diagnosis was that the GeneXpert® machine used to diagnose multi-drug resistant and extensively drug-resistant TB was not available in South Africa at the time.

"Of course, the normal TB medication did not work," says Phumeza. "When I was told I had multi-drug resistant TB, I had to swallow around 20 tablets every day for more than three years. I took close to 20,000 tablets, of all sizes and colours, along with painful injections for the first six months."

According to her doctors, Phumeza needed the drug linezolid. The private sector price for each linezolid pill was South African Rand 676 (US$ 67 at the time). A quality-assured generic version was available through the Global Fund programme for US$ 7.90 per pill, but this version could not be used in South Africa as a patent was preventing generic competition. Finally, in 2013, Phumeza gained access to linezolid through the non-governmental organization Médecins Sans Frontières.

Fortunately for other extensively drug-resistant TB patients in South Africa today, the patent on the originator product has expired and a generic company has been registered in South Africa with others pending registration. The South African government now purchases linezolid on tender for the public sector at South African Rand 100 (US$ 6.86) per pill, which is close to the lowest global price of US$ 5.35 per tablet.

"The side effects of MDR-TB drugs are a nightmare," recalls Phumeza, "skin problems and vomiting every day. I even had surgery and became deaf from the kanamycin injection."

Despite the side effects, Phumeza says she pulled through and stayed alive by daring herself to "not end up in a body bag" like others she had seen at the hospital. "Linezolid was the key player in all of this," she notes. "Without it, I am not sure if I would still be here. At the time, not many patients were lucky enough to get linezolid because it was too expensive."

In 2015, Phumeza received cochlear implants, paid for through a crowd funding website and medical insurance, which restored her hearing. "But now tell me this," asks Phumeza, "how is someone from South Africa able to pay 500,000 South African Rand [US$ 37,650 according to average 2015 exchange rates] to afford cochlear implants?"

Phumeza's story highlights the importance of patients having access not just to medicines, but to all health technologies, including vaccines, diagnostics and medical devices, in order to prevent and treat illness.

1.1 Multiple barriers to access

Many reasons exist why people do not get the healthcare they need, ranging from: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights, to name a few. WHO has recognized that the myriad of problems affecting health technology innovation and access (including unaffordability, poor quality, inappropriate use, procurement, supply chain and regulatory obstacles for both originator and generic products alike, etc.) reflect weaknesses of public health systems overall, especially in poor countries.[40]

Adequate financing of health technology R&D is needed and steps must be taken — by governments in particular — to guarantee investments that lead to equitable access, especially for poor and vulnerable populations. Robust information systems are fundamental for ensuring consistent pricing, payment and reliable supplies (for example, a well-managed supply chain can help avoid stock-outs and delays). At the point of care, service delivery must also be effective. Well-trained personnel at each stage of service delivery is critical to ensure that the right populations are identified for preventive interventions; that diagnostics are used effectively; that medicines are properly prescribed and dispensed; and that advice on the use of health technologies is conveyed in a way which encourages adherence and proper use.

WHO recommends, among other things, that closer attention is paid to the bottlenecks that prevent equitable access to medicines across populations. There must be fair and transparent selection for inclusion on national essential medicines lists, greater use of innovative pricing and financing strategies, more efficient supply models and more effective incentives for the appropriate use of medicines. While most essential medicines (as listed by WHO, see below box) are off patent, millions of people still do not have access to them.[41] Regulatory inefficiencies, poor health education, unavailability of health insurance and insufficient financial protection for those who have to pay for some or all of their treatment are major barriers to access.[42] Others note that fees, profits, taxes and tariffs along the supply chain can inflate prices significantly, but governments have been hard-pressed to track and control these increases.[43]

Box 2: WHO Essential Medicines List

The first WHO Essential Medicines List (EML) was published in 1977 in response to World Health Assembly Resolution WHA28.66 calling on WHO to assist Member States to select and procure essential medicines of good quality and at a reasonable cost. Over the past 39 years, 18 revisions of the list have been published. The selection criteria has evolved from an experience-based to an evidence-based approach, incorporating public health relevance, efficacy, safety and cost-effectiveness. [44]

The EML provides a model for at least 156 national medicines lists and is a key component of national medicine policies and medicine access initiatives. Divergence between the EML and national lists are caused, inter alia, by differences in local and regional morbidity patterns, time lags associated with new additions and country-level cost-effectiveness assessments. While the majority of medicines on previous revisions of the EML have historically been off-patent, the inclusion of new high-priced, patented treatments for hepatitis C, cancers and MDR-TB on the 2015 EML was an unprecedented development.[45]

The High-Level Panel is fully aware and acknowledges the critical importance of addressing the multiple determinants of access as well as the important work being undertaken by organizations and groups to surmount the enormous hurdles in these areas. It is critical that governments, international agencies, civil society and other relevant stakeholders work together to address the multiple determinants of access within health systems. While fully appreciating the broader context and determinants of health technology access, the High-Level Panel's recommendations focus on its mandate to address a specific and important aspect of health technology innovation and access: the policy incoherencies between trade and intellectual property rules, public health objectives and international human rights. The High-Level Panel has focused on its mandate while noting that these other issues are also of critical importance in determining access to health technologies.

1.2 Policy incoherencies

Policies that have a bearing on access to health technologies that are associated with trade, intellectual property, health and human rights were developed with different objectives and at different periods in history. Each is governed by its own legal and regulatory regime and each imposes obligations that may not align with the others. Trade and intellectual property rules were not developed with the goal of protecting the right to health, just as human rights doctrine does not primarily concern itself with promoting trade or reducing tariffs. Intellectual property regimes seek to balance the rights of inventors with the wider interests and needs of society.[46] Policy incoherencies arise when legitimate economic, social and political interests and priorities are misaligned or in conflict with the right to health. State obligations include duties not only to respect, but to protect and fulfil the right to health. This requires taking proactive measures to promote public health.

Another key aspect of incoherence lies in the misalignment between market-based models that incentivize innovation and the need to obtain treatment for patients. State obligations include duties not only to respect, but to protect and fulfil the right to health; which requires States to take proactive measures to promote public health.[47] As reaffirmed by a recent resolution of the Human Rights Council, ensuring access to medicines, and particularly to essential medicines, is a fundamental element of these obligations.[48] Yet, insufficient investment is being made in R&D for diseases that predominantly affect the poor. Furthermore, prices charged by some right holders place severe burdens on health systems and individual patients, in wealthy and resource-constrained countries alike.

The role of public funding of health technology R&D can also fuel incoherence, for example when public funding is used to subsidize private sector research, only for the fruits of such research to be priced out of reach for both public and private sector consumers.

Box 3: The right to health and the responsibilities of governments and other parties

The right to the enjoyment of the highest attainable standard of physical and mental health was first articulated in the WHO Constitution of 1948, whose preamble described it as "one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." [49] The right to health is also enshrined within Article 25 of the 1948 Universal Declaration of Human Rights, Article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) and various other international treaties, declarations and national laws, including at least 115 national constitutions. States are obliged to respect, protect and fulfil the right to health, which includes a duty to ensure that medicines are available, accessible, culturally acceptable and

of good quality.[50] The 2006 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, reiterated the obligation of states to fulfil the human right to medicines and to make full use of TRIPS flexibilities for this purpose.[51]

The 2009 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health further explored the impact of TRIPS and TRIPS-plus provisions on the right to health and in particular on access to medicines. While calling on all countries to incorporate and make full use of TRIPS flexibilities, the Special Rapporteur further called on developing and least developed countries not to introduce TRIPS-plus provisions in their national laws and on developed countries not to include such provisions in free trade agreements.[52]

Human rights law recognizes that the full achievement of all rights requires resources. There is a legal obligation of progressive realization: each state party must "take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant." [53]

The right to health also imposes a duty on states to protect the right against abuses by third parties.[54] In its "Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights," the United Nations Sub-Commission on the Promotion and Protection of Human Rights recognized that although states bear the primary responsibility to promote, respect and protect human rights, "transnational corporations and other business enterprises…are also responsible for promoting and securing…human rights". [55]

While the Universal Declaration of Human Rights and the ICESCR protect the right to health and the right to enjoy the benefits of science, they also guarantee the rights of scientists, artists and authors to protect their work's integrity and reap its financial benefits.[56] However, it is worth emphasizing that the United Nations Committee on Economic, Social and Cultural Rights (CESCR), an independent body of experts that monitors ICESCR implementation, clarified that natural persons, not corporations, have human rights to these protections. This protection, the Committee wrote, "is a human right, which derives from the inherent dignity and worth of all persons," a fact that "distinguishes human rights from most legal entitlements recognized in intellectual property systems." [57]

1.2.1 The TRIPS Agreement and the right to health

Since the emergence of formal patent statutes over 500 years ago, governments have granted temporary monopolies with conditions attached, such as, for instance, requiring the right holder to train local artisans in the craft and technology that produced the product.[58] The rules that spur innovations and govern their protection and diffusion evolve in accordance with the exigencies of trade. It remains important, however, that national and multilateral policies balance objectives: trade promotion and liberalization versus the protection of domestic industries and citizens. The first formal multilateral patent treaty, the 1883 Paris Convention for the Protection of Industrial Property, imposed a set of global norms, but it also left signatories significant room to use intellectual property to pursue national goals. States retained the discretion to determine the duration of a patent under national law and to exclude certain fields of technology from patentability. The Convention also provided for the revocation of patents and the issuance of compulsory licences to remedy abuses by right holders.[59]

In 1986, when trade negotiations leading to the establishment of the WTO commenced, 50 countries did not provide patent protection on pharmaceutical products.[60] This remained essentially unchanged for the next decade, although some Andean countries began adopting pharmaceutical patent protections in the 1990s. In 1995, with the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the aegis of the WTO, a new and unprecedented era of global intellectual property norms began. The TRIPS Agreement was a watershed in the evolution of intellectual property protection. Its provisions required WTO Members subject to the transition periods then available for developing countries (and still available to LDCs) to provide a 20-year period of patent protection on health technologies. WTO Members were required to implement the TRIPS Agreement as a condition of their membership, which most governments saw as crucial in a global economy.

For many countries and public health proponents, provisions embodied in the TRIPS Agreement presented a policy dilemma. On the one hand, governments embraced the agreement for the economic benefits of increased trade. On the other, the obligation to grant patents on medicines and other health technologies would affect the availability and affordability of health technologies. This obligation had a clear potential to strain national budgets and to place health technologies out of the reach of those in need. Meanwhile, human rights law—both binding international treaties and national statutes—required governments to progressively realize the highest attainable standard of health.[61]

To address these tensions, negotiators included safeguards in the TRIPS Agreement that could be used to promote the right to health. Article 7, for instance, provides that intellectual property rights should advance technological innovation and the dissemination of technology "to the mutual advantage of producers and users…in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Article 8 (1) provides that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement."

The TRIPS Agreement also included 'flexibilities' that enable signatories to tailor and employ national intellectual property law, competition law, medical regulations and procurement laws to fulfil their human rights and public health obligations.

Among the most discussed TRIPS flexibilities are compulsory licences, wherein a government imposes the terms under which a patented product can be used or produced in generic versions without the consent of the patent holder.[62]

Box 4: Public health-related TRIPS flexibilities: A snapshot [63]

Flexibility	TRIPS Article	Explanation
Parallel imports	6	Goods legitimately placed on another market may be imported from another market without permission of the right holder because of the exhaustion of the patent holder's exclusive marketing rights.
Patentability criteria	27	WTO Members may develop their own definitions of 'novelty,' 'inventive step' and 'industrial application.' They can also refuse to grant patents for certain subject matter, e.g. plants and animals.
General exceptions	30	WTO Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.
Compulsory licensing	31	A non-voluntary licence may be granted by a duly authorized administrative, quasi-judicial or judicial body to a third party to use a patented invention without the consent of the patent holder, subject to the payment of adequate remuneration in the circumstances of each case.
Government use	31	A government authority may decide to use a patent without the consent of the patent holder for public, non-commercial purposes, subject to the payment of adequate remuneration in the circumstances of each case.
Competition-related provisions	8, 31(k), 40	Members may adopt appropriate measures to prevent or remedy anti-competitive practices relating to intellectual property. These include compulsory licences issued on the basis of anti-competitive conduct and control of anti-competitive licensing.
Transition periods	65, 66	LDCs are not required to provide patent or data protection in general until 1 July 2021 and on pharmaceutical products are not required to grant or enforce patents or data protection until 1 January 2033, or a subsequent date as agreed by WTO Members.

A few years after the TRIPS Agreement came into force, the context of the burgeoning AIDS pandemic at that time made it clear that WTO Members had yet to reach consensus on how to interpret and apply the flexibilities within the agreement.[64] Many WTO Members sought consensus on interpretation of the TRIPS Agreement. An accord was finally reached and is embodied in the Doha Declaration on the TRIPS Agreement and Public Health (2001). The Doha Declaration stresses that TRIPS "can and should be interpreted and implemented" to support the "right to protect public health [and] promote access to medicines for all," including the sovereign determination of the grounds under which a compulsory licence may be issued.[65]

Box 5: The Doha Declaration on the TRIPS Agreement and Public Health

Notwithstanding the public health flexibilities included in the TRIPS Agreement, in the late 1990s, in practice, the right to make use of these flexibilities by governments of developing countries was challenged by the pharmaceutical industry and by governments of a number of high-income countries. In this context, WTO Members sought to reach consensus on the relationship between the TRIPS Agreement and public health.

In April 2001, the TRIPS Council held a Special Session to discuss the right of WTO Members to use TRIPS flexibilities. After protracted negotiations, the Doha Declaration was adopted on 14 November 2001. The Doha Declaration affirms the rights of WTO Members to use flexibilities in the TRIPS Agreement to promote public health objectives. The Doha Declaration states:

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, 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 licences and the freedom to determine the grounds upon which such licences 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 most-favoured-nation and national *treatment provisions of Articles 3 and 4."*
6. *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.*
7. *We reaffirm the commitment of developed country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members pursuant to Article 66.2. 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 the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.*

Since the TRIPS Agreement came into effect, bilateral and regional free trade agreements (FTAs) concluded by several governments have progressively expanded and deepened patent and test data protections on health technologies. Such provisions further exacerbate policy incoherence by narrowing the options provided by the TRIPS Agreement and the Doha Declaration for governments to ensure that intellectual property protection and enforcement does not undermine their human rights obligations and public health priorities. A number of provisions found in bilateral and regional FTAs exceed the minimum standards for intellectual property protection and enforcement required by the TRIPS Agreement. These provisions may impede access to health technologies, including those requiring governments to ease standards of patentability[66], drug regulatory authorities to link marketing approval to the absence of any claimed patent[67] and the requiring of test data exclusivity instead of test data protection, to list a few.[68]

The recent Trans-Pacific Partnership Agreement (TPP), which is yet to come into force, is emblematic of the new generation of bilateral and multilateral trade and investment agreements which include 'TRIPS-plus' provisions that progressively ratchet up intellectual property protection and enforcement.[69] This new generation of trade and investment agreement often includes dispute settlement mechanisms that establish arbitration processes outside of national courts and allow private firms to challenge national laws for depriving them of future profits. Other provisions restrict government ability to regulate pharmaceutical prices and reimbursement mechanisms. Such provisions significantly reduce the scope of measures that national governments can use to pursue public health priorities and fulfil the right to health. Ensuring that future trade agreements do not interfere with policies that guarantee the right to health for all is essential for resolving the incoherence between trade agreements and the human right to health. [70]

The High-Level Panel noted that a number of contributions pointed to a progressive de-prioritization and erosion of human rights in the implementation of intellectual property law and policy, both under TRIPS and as a result of recent trade agreements. A number of calls, including to the High-Level Panel, have been made for a new United Nations instrument to uphold universal human rights in laws, policies and actions that affect health technology innovation and access. The High-Level Panel did not reach consensus on this proposal. While recognizing the importance of these calls, the High-Level Panel concluded that human rights and other obligations as they relate to access to essential medicines already exist and are embedded in United Nations instruments, guidance and decisions of human rights bodies and in a number of national and regional legal instruments. If given proper effect and properly observed, the provisions of TRIPS and the Doha Declaration would give rise to the necessary protections and required balances to protect the human right to health in trade and intellectual property matters. To revise or update these existing rights would be to concede ground to any argument of their derogability. Therefore, and in light of the urgency of addressing the health technology innovation and access challenges in line with its mandate, members of the High-Level Panel agreed in its recommendations to reinforce those rights in

current existence and underline the need for greater attention, monitoring and enforcement to ensure that these rights are not undermined and are actively pursued.

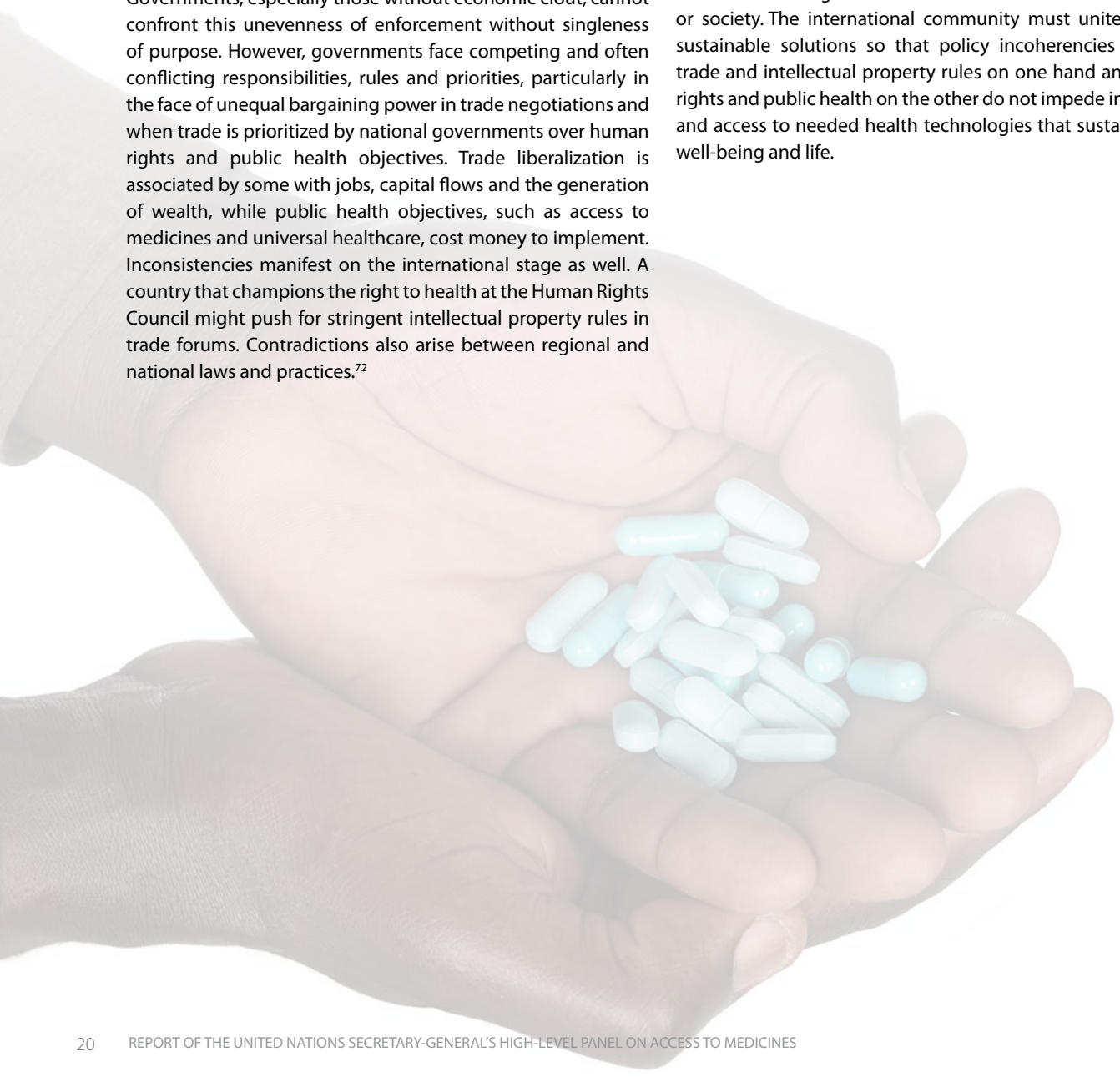
1.2.2 Incoherencies and asymmetries of power

The Doha Declaration confirms that the TRIPS flexibilities are not exceptions, but rather, a fundamental part of the TRIPS machinery. Yet, numerous incoherencies and troubling practices have obstructed sovereign freedom of governments in using flexibilities to promote public health.[71] One critical incoherence is the uneven application of health and trade policy within and among WTO Members. The signatories to TRIPS have not pursued implementation of the flexibilities that protect the health of their populations with the same vigour as they have introduced and enforced the intellectual property protections. The right to health and the right to benefit from scientific progress were articulated in the Universal Declaration of Human Rights. But, while inalienable and universal, their enforcement and accountability mechanisms pale in comparison to those found in intellectual property law.

Governments, especially those without economic clout, cannot confront this unevenness of enforcement without singleness of purpose. However, governments face competing and often conflicting responsibilities, rules and priorities, particularly in the face of unequal bargaining power in trade negotiations and when trade is prioritized by national governments over human rights and public health objectives. Trade liberalization is associated by some with jobs, capital flows and the generation of wealth, while public health objectives, such as access to medicines and universal healthcare, cost money to implement. Inconsistencies manifest on the international stage as well. A country that champions the right to health at the Human Rights Council might push for stringent intellectual property rules in trade forums. Contradictions also arise between regional and national laws and practices.[72]

Even when there is no incoherence in policy and law, inequality of bargaining power among domestic government departments and the asymmetry of power between well-resourced and poorer countries and between corporations and citizens can facilitate interpretations of the law that fuel incoherence.[73] Governments and corporations sometimes threaten political or economic retaliation as a means of illegitimately pressuring others into forgoing their TRIPS flexibilities.[74] Such actions are against the letter and spirit of the TRIPS Agreement and the Doha Declaration. They also undermine efforts by governments to meet their human rights obligations.

Policy incoherence is not always a matter of law. It is also a matter of interpretation and application, shaped by priorities and politics. Human rights are fundamental, universal entitlements that people inherently acquire by virtue of their birth. In comparison, intellectual property rights are "one policy tool among many for encouraging innovation and technological research and development." [75] Intellectual property rights are temporary, revocable, transferable privileges granted by states and can be suspended or revoked under certain conditions laid out in the TRIPS Agreement when it is in the interest of the state or society. The international community must unite to build sustainable solutions so that policy incoherencies between trade and intellectual property rules on one hand and human rights and public health on the other do not impede innovation and access to needed health technologies that sustain health, well-being and life.



2. INTELLECTUAL PROPERTY LAWS AND ACCESS TO HEALTH TECHNOLOGIES

Intellectual property refers generally to legal rights resulting from intellectual activity in the fields of industry, science, or art. Through patents, which are one form of intellectual property provided for inventions, countries grant the holders of intellectual property time-limited control on the use of this property. Patents are sets of exclusive rights, granted by a state authority, or a patent organization recognized by the state to inventors or assignees, which could be physical persons, or legal entities, including corporations. Patents are granted for a limited period of time in exchange for the detailed public disclosure of the invention.[76]

It is these patents, along with other forms of intellectual property rights and various types of direct or indirect government or public support, that have enabled right holders to generate the revenues that have contributed to the R&D of medicines, vaccines and diagnostics over the last half century or so that have benefited health and human development.[77] While some assert that intellectual property policy is working as intended,[78] others note that patent protection and enforcement should better balance the interests of the holder of the property rights and the interests of society,[79] and that the needs of the poorest still are not met. When profit is the primary engine for innovation, public health needs can be neglected and the right to health impeded. How can current laws, policies and practices work better to match the objectives of intellectual property policies with those of human rights obligations and public health priorities? To address the misalignment between public health objectives and trade and intellectual property protection, it will be necessary to identify the models and mechanisms that can remedy shortcomings in the existing intellectual property regime.[80]

As noted earlier, governments retained significant flexibility to adapt their patent laws to advance public health objectives before the TRIPS Agreement. For instance, Canada made regular use of compulsory licensing to promote local production of pharmaceuticals, resulting in some of the lowest consumer prices for medicines in the industrialized world. Between 1969 and 1992, there were 1,030 applications to import or manufacture medicines under these licences, of which 613 were granted by authorities.[81] When the Republic of Korea adopted a Patent Act in 1961, it excluded foodstuffs, chemicals and pharmaceuticals from patentability and only allowed for 12 years of patent protection on other fields of technology.[82] India is the most often cited example of how a government used their freedom to adapt domestic intellectual property laws to meet national objectives. Concerned in part by high prices, India passed a Patent Act in 1970 that excluded pharmaceutical products from patent protection. This reduced the number of patents by as much as 75%, according to some estimates, and paved the way for India's thriving generic medicines industry.[83] These are just a few mechanisms that have been used by governments out of a range of voluntary and non-voluntary mechanisms available to increase access to health technologies and promote the right to health.

While the price of health technologies is influenced by a variety of factors, including the size of the potential market and the results of negotiations with public and private insurers, intellectual property concerns also play a central role. Article 7 of the TRIPS Agreement claims that intellectual property aims to foster innovation and thereby improve societal well-being, but paradoxically, it achieves this in the short-term by creating a monopoly whereby patent holders bear significant power over end prices, rather than the usual open market. For some countries, prices of innovative health technologies have increased more quickly in recent years than the average consumer price index.[84] In some cases, the application of patent protections required by the TRIPS Agreement can conflict with the right to health in rich and poor countries alike, thus resulting in policy incoherencies and tensions. IP rights confer patent monopolies on the right holder, who in turn often charges whatever price the market will bear.

For example, over the past decades, revolutionary treatments for cancer have been developed. But, these life-saving treatments, while under patent protection, can be financially unsustainable, particularly when the costs have to be borne by the patients themselves. Even in countries with public and/or private healthcare systems, patients are frequently saddled with unmanageable out-of-pocket expenses.[85] In the United States, prices of cancer medicines have almost doubled from a decade ago, averaging from US$ 5,000-10,000 per month. Of the 12 medicines approved by the United States Food and Drug Administration (FDA) for various cancer indications in 2012, 11 were priced above US$ 100,000 per year.[86] In rich and poor countries with public health systems, government expenditures on health technologies is a significant proportion of overall government and health department expenditure, diverting resources away from other essential health services.[87]

Box 6: The impact of the high cost of health technologies

"Sofosbuvir is an important breakthrough in the treatment of patients with chronic hepatitis C. The problem is that a one-time treatment costs between 48,000 and 96,000 Euros. The Netherlands has an estimated 20,000 patients with this disease. The supplier defends this price in part by pointing to the great value to the patient and to those affected by the patient's illness. But such costs make healthcare unaffordable. If the Netherlands continues in this way, it will become nearly impossible to reimburse patients for these medications."

Contribution from the Ministry of Foreign Affairs, the Kingdom of the Netherlands, 27 February 2016

2.1 Voluntary licences

Voluntary licences are private contracts entered into between right holders and third parties to facilitate the market entry of more affordable treatments.[88] Voluntary licences enable the right holder to maintain a degree of market control by selecting the countries where voluntary licences are negotiated and concluded. The terms and conditions of voluntary licences, such as the number of patients that can be treated, the types of suppliers from whom active pharmaceutical ingredients must be sourced and the amount of royalty paid to the right holder, can vary widely. The level of transparency in licensing agreements executed by the UNITAID-backed Medicines Patent Pool (MPP), in which all licences are publicly available, is laudable and rare. Voluntary licences can be an important enabler of treatment access. For example, in less than four years, licences negotiated through the MPP are estimated to have generated US$ 120 million in savings globally and supplied seven million patient-years of WHO-recommended ARV medicines.[89]

To date, voluntary licensing mechanisms established to support patent pooling have typically focused their efforts on health technologies for specific diseases. The decision of the MPP, therefore, to broaden its scope beyond HIV to TB and hepatitis C in late 2015 is an important development.[90]

Geographical limitations are another traditional downside of voluntary licences. Irrespective of disease burdens and in some cases high levels of income inequality, developed countries, as well certain developing countries with comparatively high levels of per capita income are usually excluded from the scope of licences, as right holders reserve the right to identify countries where they intend to sell the product directly or through other agreements.[91] An example of this is the voluntary licences concluded between Gilead and various generic companies covering 101 countries for the hepatitis C medicine, sofosbuvir. The high prices at which the products are sold to governments outside of its geographical scope can create tensions and raise serious concerns around access.[92]

2.2 TRIPS flexibilities

As mentioned above, even though the TRIPS Agreement ushered in a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important public health flexibilities that can be used to adapt their intellectual property law, policies and practices to meet human rights and public health objectives. These include the ability to determine patentability criteria, issue compulsory licences, authorize parallel importation, apply general exceptions and employ competition laws to limit and remedy the abuse of intellectual property rights in domestic legislation. Patentability criteria, compulsory licences and competition law will be discussed below.

2.2.1 Patentability criteria

The TRIPS Agreement does not define patentability requirements per se, except to say that an invention must be novel, involve an inventive or non-obvious step and be industrially applicable or useful.[93] This leaves considerable discretion to governments to define and apply these criteria within national legislation.[94] At one end of the spectrum are national authorities who either do not undertake substantive patent examination or who interpret the criteria broadly, granting secondary patents that in effect extend the original patent based on varying methods of use, formulations, dosages and forms of constituent chemicals.[95] At the other end of the spectrum are national authorities with provisions stating that a mere discovery of a new form of a known substance that does not improve efficacy is not patentable.[96] Similar to the use of flexibilities in general countries applying a public health-based interpretation of patentability criteria have faced pressure against such an interpretation and application in their national laws.[97]

In some instances, secondary patents are granted for minor but important changes to an existing product. Secondary patents can, however, prolong exclusivity (commonly known as 'evergreening'). In doing so, entrance of generic or competing products can be curtailed and prices remain high, thereby limiting patient access to health technologies.[98] Furthermore, secondary patents can create legal uncertainty around the patent status of a health technology, which in turn discourages entities from procuring generic versions of products for fear of patent infringement.[99] In some instances, however, changes to existing medicines may add important therapeutic value by, for example, helping patients to tolerate the medicine better. This, in turn could promote competition with the original medicine. Secondary patents may also be important for the development of safer, less toxic and more effective health technologies.[100]

Since the TRIPS Agreement entered into force, patents have been increasingly seen as a potential source of income for health researchers with the result that more complex patenting strategies are being adopted. Patent right holders and originators can file multiple applications for the same invention that create a set of overlapping patent rights that may be difficult to negotiate (known as 'patent thickets'). The result of these practices is that a party that seeks to commercialize new technology may need to obtain permission from multiple patentees. A 2011 patent landscape analysis found that the antiretroviral medicine ritonavir, for instance, was protected by 805 patent families held by the originator and other research-based companies.[101]

Empirical studies of patent thickets show varied results, highlighting potential impacts which range from: 1) discouraging others from undertaking research on competing products; 2) high licensing costs; 3) refusal of the patent holder to grant a licence to one or more of the patented technologies; 4) competing products potentially infringing on a number of patents and thus requiring multiple royalty payments (known as 'royalty stacking'); and 5) difficulties associated with inventing around a group of patents.[102] In one study of biomedical researchers, three quarters of the researchers reported encountering difficulties in accessing patented technologies, which resulted in half of them changing their research plans and 28% abandoning their plans altogether. Patent thickets also affect commercial decisions by would-be makers, sellers

and importers of medicines and health technologies.[103] Governments can adopt legislation to limit excessive patenting that stifles health technology R&D and access. The application of public health-sensitive guidelines in country patent offices may be an important policy tool to improve health technology access.[104]

2.2.2 Compulsory licences

The TRIPS Agreement preserves the right of WTO Members to grant compulsory licenses on a number of grounds, including instances in which a license is in the public interest, there are abuses of rights or anti-competitive conduct, or for public non-commercial use, to name a few. Compulsory licences are an important policy tool for government authorities to promote access to health technologies. With a compulsory licence, a government imposes the terms under which a licence on a patented product may be used in that country by a third party without the consent of the patent holder. While the state denies the patent-holder a monopoly, it does not deny them remuneration—the beneficiary of the licence pays a royalty. The right holder retains its exclusive rights, except with regard to the compulsory licensee. The Doha Declaration dispelled the myth that compulsory licences should be limited to emergency situations by confirming that WTO Members were free to determine the grounds under which compulsory licences could be issued.

The principle of compulsory licensing has been an important part of patent law for centuries,[105] and the licences have been used by governments in all countries to serve the interests of society or the state, subject to the payment of a royalty to the right holder.[106] Some have expressed concerns that the prospect of compulsory licences drives off investment in countries that issue them[107] and there is apprehension that these governments could be subjected to retaliation. The threat of compulsory licences has been used by governments to obtain price reductions from patent holders, who generally found the lower negotiated prices preferable to receiving royalties.[108] In 2007, after protracted negotiations, the Brazilian government issued a compulsory licence for efavirenz, an important antiretroviral medicine then used by one-third of Brazilians use on treatment through the national programme. After the licence was issued, the price dropped from US$ 1.60 per dose to US$ 0.45 per dose for the imported generic version of the medicine.[109]

While most governments have compulsory licensing provisions in their patent legislation, the effectiveness of such laws is mixed. The High-Level Panel received a number of contributions making the case for international, regional and national mechanisms to enable more expedient and user-friendly processes for granting compulsory licenses. In particular, the High-Level Panel engaged in a robust debate as to whether governments should, in the interests of meeting human rights and public health objectives, be encouraged to implement a system of compulsory licensing in national legislation that is effectively automatic by way of its predictability and implementation, provided the requirements in Article 31 of the TRIPS Agreement are met. While a majority of Panel Members were in favour of such an approach, a sizable minority of Panel Members were not, because of concerns over the potential incompatibility of such measures with the TRIPS Agreement and the unintended consequences that may result from such an approach. The High-Level Panel therefore did not reach consensus on this particular issue. The High-Level Panel nonetheless urges that national laws should be drafted in a way that facilitates the prompt and expedient use of a compulsory licence or government use for non-commercial purposes of a patent, including criteria to determine the remuneration for the right holder. As the Doha Declaration notes, governments should retain the freedom to determine the grounds under which compulsory licences are issued.

The TRIPS Agreement requires that health technologies produced under compulsory licence be predominantly for domestic use. This poses little problem for countries with significant biomedical manufacturing capacity. However, for countries with no or insufficient health technology manufacturing capacity, this can pose a significant challenge. The "Paragraph 6 decision," was a temporary waiver agreed by WTO Members on 30 August 2003 meant to address this problem by removing the limitation to predominantly supply the local market. Two years later, on 6 December 2005, WTO Members agreed to submit the temporary waiver of 2003 as a Protocol for the first, and so far only, amendment of the TRIPS Agreement, subject to the acceptance of two-thirds of WTO Members.[110]

There are differing opinions as to why the "Paragraph 6 decision" has only been used once in 13 years. Some note that multilateral health financing has removed the need for resource-constrained countries to use it. Others argue that it is too complex to be used. The only time the mechanism was used, it proved to be complex and cumbersome[111] and serious questions remain as to its effectiveness.[112] More than 10 years after WTO Members agreed to transform the temporary waiver into an amendment of the TRIPS Agreement, the amendment is yet to be accepted by two-thirds of WTO Members.[113] At a time of increased political commitment to enhancing local pharmaceutical production in developing countries,[114] attention should be paid to incorporating efficient, easy to use compulsory licensing provisions into domestic legislation.

2.2.3 Competition law

Complementary tools to intellectual property laws, such as competition law, provide an important market-stabilizing effect on anti-competitive behaviour. Examples of anti-competitive practices in the health technologies sector include bid rigging, price fixing, exclusionary supply arrangements and anti-competitive mergers and acquisitions. Relating to intellectual property, anti-competitive practices might include restrictive licensing conditions, abusive patenting (e.g. to block generic entry) and excessive pricing.

Article 8(2) of the TRIPS Agreement[115] provides an insufficiently used opportunity for governments to prevent abuse of intellectual property rights by right holders and achieve price reductions for health technologies depending on the provisions

of local competition laws. One such avenue is competition law and policy, which can be used to balance proprietary interests with economic and social interests to advance public welfare.[116]

Competition policy has been used to remedy anti-competitive conduct in the biomedical industry and to promote treatment access in many countries.[117] Various organizations have published guidance on competition law and offer support to WTO Members who may wish to regulate anti-competitive conduct in the health sector.[118] Competition policies are important levers that governments can employ to ensure that health technology markets operate competitively and that the public benefits from low prices and innovation. Should governments pay closer attention to competition law, it could serve as an important policy tool for increasing access to health technologies.

2.3 National coherence

Incorporating public health-related TRIPS flexibilities into national intellectual property law typically cuts across many government departments and ministries—trade and industry, economic development, science and technology, health, justice, foreign affairs, national planning and finance, to name the most obvious ones. Ministries in most national cabinets operate in an asymmetrical power structure and do not necessarily coordinate their objectives and actions with each other, thus fuelling policy incoherence at the national level. Special measures are needed to promote national coherence so that public and private interests are better balanced.[119] Tensions between ministries responsible for the promotion of trade and the protection and enforcement of intellectual property on the one hand and those responsible for public health should not result in the prioritization of trade over health. The very nature of fundamental human rights requires that they outweigh private interests under national law.

The flexibilities available in the TRIPS Agreement provide WTO Members with significant latitude to adapt and enforce their laws and policies to advance their national interests. Country-level, inter-sectoral coordination could be an important catalyst to supporting governments to translate policy space in TRIPS into coherent and comprehensive national laws. United Nations agencies and multilateral organizations should be supporting governments in the drafting of public health-sensitive national laws and policies, providing technical and advocacy support for using TRIPS flexibilities and helping governments negotiate trade agreements that incorporate an evaluation of public health and human rights impacts during and after negotiations, not according to their mandates, but in response to the public health needs of countries.

2.4 Limitations to the use of TRIPS flexibilities

The ability of United Nations Member States to achieve the Sustainable Development Goals and targets will depend on well-functioning national policies, including those relevant to health technology innovation and access. In particular, access to the fruits of innovation, including access to health technologies, requires that both the exclusive rights granted to innovators and the limitations and exceptions to those rights provided under national and international law are fully recognized and respected. Maintaining this balance is essential to realization of the public welfare and development objectives of the patent system and the TRIPS Agreement.

However, many governments have not used the flexibilities in the TRIPS Agreement. The reasons for this vary. In some cases, governments may not see the need to use them because national treatment programmes are presently being sustained by health financing mechanisms, such as the Global Fund and PEPFAR.[120] In other countries, where multilateral health financing is not available, there may be political will but capacity constraints may impede their effective use. Intellectual property laws are complex; technical assistance tailored to specific country contexts and needs while drawing on international experiences and good practices around improved coordination between different ministries could strengthen the negotiating ability of countries to ensure national and public health objectives are achieved.

Box 7: Obstacles to the use of TRIPS flexibilities

The Doha Declaration reaffirmed the rights of WTO Members to utilize flexibilities available under the TRIPS Agreement for the purpose of promoting the right to health and public health objectives. Despite these pronouncements, the sovereign right to issue compulsory licenses provided for by TRIPS has been stymied by threats of retaliation from governments and corporations against countries who have followed the prescribed process set out in TRIPS. The ensuing cloud of controversy, intimidation and legal incertitude associated with compulsory licenses have weakened the bargaining position of many WTO Members. It has also impeded the possibility of creative arrangements between governments and corporations with respect to strategies for the production and distribution of health technologies.

One such example is Thailand's 2006 decision to import generic versions of the antiretroviral medicine efavirenz from India under compulsory licence. This decision was met with hostility from the manufacturer, Merck, and the United States Government, which questioned the legality of the compulsory licence and pressed Thailand to rescind its decision. Thailand's subsequent decision to issue two further compulsory licences in 2007 for lopinavir/ritonavir and clopidogrel also resulted in retaliatory measures. In response, Abbott withdrew from the Thai market all medications awaiting registration and refused to register any new pharmaceutical products in the country, thereby denying patients access to the heat resistant form of lopinavir/ritonavir for which no generic equivalent existed,[i] although it later rescinded its decision. The European Trade Commissioner wrote to the Thai government criticizing its use of compulsory licences as "detrimental" to medical innovation, noting that such approaches could lead to Thailand's isolation from the global biotechnology investment community and urging negotiations

with Sanofi-Aventis and other right holders.[ii] The United States Trade Representative elevated Thailand to its Priority Watch List in the Special 301 Report and withdrew duty-free access to the American market for three Thai products under the United States Generalized System of Preferences.[iii]

A letter from the Permanent Mission of Colombia to the United Nations, as well as letters from civil society groups addressed to the co-chairs of the High-Level Panel, brought to light developments in Colombia.[iv] In early 2016, the Ministry of Health of Columbia adopted resolution 2475, declaring that access to imantib, a medicine that appears on the WHO Essential Medicines List, was of "public interest" for the treatment of leukaemia.[v] The resolution was a pathway for the issuance of a compulsory licence. The letters chronicle attempts by various domestic and foreign parties to dissuade the Colombian government from issuing a compulsory licence as provided for by the TRIPS Agreement and the Doha Declaration.

[i] Wibulpolprasert, S., *et al.* (2011) Government use licenses in Thailand: The power of evidence, civil movement and political leadership. *Globalization and Health,* 7(32)).
[ii] A copy of the letter is available from: https://www.wcl.american.edu/pijip_static/documents/mandelson07102007.pdf [Accessed 9 September 2016].
[iii] Yamabhai, I., *et al.* (2011) Government use licences in Thailand: An assessment of the health and economic impacts. *Globalization and Health,* 7(28); ITPC (2015). The campaign for use of compulsory licensing in Thailand. *Make Medicines Affordable* [online]. Available from: http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/ [Accessed 28 June 2016].
[iv] The letters from the Permanent Mission of Colombia to the United Nations and civil society groups are available from:
http://www.mision-salud.org/2016/07/06/carta-abierta-al-panel-de-alto-nivel-sobre-acceso-a-medicamentos-de-las-naciones-unidas/ [Accessed 9 September 2016]
http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d2e998cd0f68c542159efc/1473440152256/Letter+from+Colombia.pdf [Accessed 9 September 2016]
[v] The resolution is available from: https://www.minsalud.gov.co/Normatividad_Nuevo/Resoluci%C3%B3n%202475%20de%202016.pdf

There are also instances where undue political and economic pressures have been used to dissuade governments from using the flexibilities that could protect public health.[121] Any form of undue pressure by governments designed to penalize other governments for exercising any of the powers they enjoy pursuant to the flexibilities available in the TRIPS Agreement violates the integrity and legitimacy of the system of legal rights and duties created by TRIPS, as confirmed by the Doha Declaration. Such actions undermine the efforts of governments to meet their human rights obligations as well as their inalienable duty to protect health. Should governments make full use of the flexibilities in the TRIPS Agreement, they can protect and advance public health objectives. WTO Members must help safeguard the legitimate rights of individual Members to adopt and implement flexibilities in the TRIPS Agreement as reaffirmed by the Doha Declaration.

The political pressure exerted on governments to limit the use of TRIPS flexibilities in some instances has been accompanied in recent years by a proliferation of initiatives aimed at intensifying intellectual property protection and enforcement measures. TRIPS-plus provisions in recent free trade agreements, such as the TPP, or in agreements concluded as a condition for acceding to the WTO, exacerbate these incoherencies by expanding intellectual property protection and enforcement and corporate prerogatives to unprecedented levels. The TPP, inter alia, grants exclusivity to test data, including new indications for existing medicines and biologics (medical products derived from living organisms). TRIPS-plus provisions generally extend the scope of what is patentable and also the duration of exclusivity protection. Dispute resolution under the TPP has turned what were previously civil infractions, such as trade secret theft, into criminal offenses.[122]

The duty borne by governments to protect the rights of their citizens by using TRIPS flexibilities extends to the conclusion of TRIPS-plus commitments. Agreeing to TRIPS-plus provisions in the hopes of gaining market access for agricultural or manufactured goods first requires empirical evidence of the consequences. Failure to conduct robust impact assessments before concluding such agreements is tantamount to a neglect of state duties to safeguard the right to health.

Box 8: Examples of TRIPS-plus provisions[123]

TRIPS-plus provision	Examples of their use in trade agreements	Explanation
Patents for new uses or methods of using a known product	US-Korea Free Trade Agreement (FTA) (Art. 18.8(1)); US-Australia FTA (Art. 17.9(1)); TPP (Art. 18.37(2)).	Governments must provide patent protection for new uses or methods of using known products.
Prohibition on pre-grant patent opposition	US-Singapore FTA (Art. 16.7(4)); US-Korea FTA (Art. 18.8.4).	Prohibition on challenges to the validity of a patent prior to issuance.
Test data exclusivity periods	WTO TRIPS Checklist for Russian Accession (WT/ACC/9, p. 13); US–Chile FTA (Art. 17(10)(1)); US-Morocco FTA (Art. 15(10)(1)); US–Bahrain FTA (Art. 14(9)(1)(a)); US–Singapore FTA (Art. 16(8)(1)); US-Australia FTA (Art. 17(10)(1)); TPP (Arts. 18.50 and 18.51).	Drug regulatory authorities cannot use or rely on clinical studies and data developed by the originator company to register the generic equivalent of a medicine for a given period of time following registration.

Patent term extensions for 'unreasonable' regulatory or marketing delays	Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) (Arts. 15(9)(6) and 15(10)(2)); US-Bahrain FTA (Art. 14(8)(6)); US–Chile FTA (Arts. 17(9) and 17(10)(2)(a)); US–Singapore FTA (Arts. 16(7)(7) and 18(8)(4)(a)); US–Australia FTA (Arts. 17(9)(8) and 17(10)(4)); US–Morocco FTA (Arts. 15(9)(7) and 15(10)(3)); TPP (Arts. 18.46(3) and 18.48(2)).	Patent terms are extended in case of 'unreasonable' delay caused by drug regulatory authorities or patent offices in granting regulatory or marketing approval.
Patent linkage	Arts. 19(5)(3) of CAFTA-DR; 17(9)(4) of US–Chile FTA; 15(9)(6) of US–Morocco FTA; 16(7)(5) of US–Singapore FTA; 14(8)(5) of US–Bahrain FTA; Art. 18.53 of TPP.	Drug regulatory authorities cannot approve a generic version of a medicine that is under patent without the consent of the patent holder, thereby obliging public authorities to 'enforce' private intellectual property rights.
Limits on compulsory licensing grounds	US-Jordan FTA (Art. 4(20)); US-Singapore FTA (Art. 16(7)(6)); US-Australia FTA (Art. 17(9)(7)).	The use of compulsory licences is confined to specific circumstances, for example, remedying anti-competitive practices.
Limits on parallel imports	US-Morocco FTA (Art. 15(9)(4)); US-Australia FTA (Art. 17(9)(4)); US–Singapore FTA (Art. 16(7)(2)).	The importation of pharmaceutical products from other markets under the principle of international or regional exhaustion is restricted or entirely prohibited.
Enforcement of intellectual property rights	US-Singapore FTA (Art. 16.9); US-Vietnam FTA (Arts. 14-15); Japan-Indonesia FTA (Arts. 119, 121); Japan-Malaysia EPA (Art. 127); Japan-Thailand EPA (Art. 140); US-Vietnam FTA (Art. 14.1); US-Australia FTA (Art. 17.11(27)); US-Laos FTA (Art. 25); TPP (Art. 18.76).	Enhanced obligations regarding border measures, civil and administrative procedures, remedial provisions and the criminalization of certain violations beyond what is required by the TRIPS Agreement.

2.5 Intellectual property generated from publicly-funded research

Because the United States plays a central role in global innovation, its R&D and access policies influence other actors, including private and public sector donors and foundations, and impact on access to the fruits of technology worldwide. The National Institutes of Health (NIH) of the United States is by far the largest funder of health technology innovation, contributing over US$ 26 billion in 2013.[124] In 1980, the United States Congress enacted the Bayh-Dole Act, which, under the stated objective of promoting utilization of publically-supported inventions through institutional use of patents,[125] ushered in a new model of incentives for federally-funded academic R&D.

Bayh-Dole represented a significant departure from the status quo. Prior to 1980, the general practice at most academic research institutions was to share scientific findings through publication, and inventions arising from federal funding had to be assigned to the federal government, while very few were licensed out.[126] Now under Bayh-Dole, universities and public research institutions are allowed to patent the results of federally-funded research and to license private enterprises to develop them.[127] The United States Government retains a non-exclusive license to practice under the patent rights and the right, under specific circumstances, to license the invention to a third party, without the consent of the patent holder. Other governments have since passed laws modelled on Bayh-Dole.[128]

The Bayh-Dole Act has played a prominent role in the commercialization of biomedical technologies. Between 1980 and 2010, 154 FDA-approved medicines that were developed at United States research institutions were brought to market.[129] While Bayh-Dole has been credited with spurring economic development in the United States, royalty revenue—with important exceptions—is generally not that profitable for the patent holder. Universities, at times, pressure researchers to patent their work, seeing royalties as a potential revenue source, which in many cases isn't significant. For example, in 2006, United States universities, hospitals and research institutions derived US$ 1.85 billion from technology licensing compared to US$ 43.58 billion from federal, state and industry funders that same year. Technology licensing in that year accounted for less than 5% of total academic research dollars.[130]

Although intended to speed the transfer of scientific discovery from lab to marketplace for public benefit, critics contend that Bayh-Dole has had some unintended consequences, particularly when scientific research is constrained by the existence of a patent.[131] For example, indiscriminate patenting of research tools can potentially create unnecessary hurdles to accessing materials and technologies necessary for basic research.

Bayh-Dole allows recipients of federal support to negotiate flexible licensing terms and conditions, including through the use of voluntary licenses, or choosing to publish and to not seek patent protection, among others. But because many inventions licensed under Bayh-Dole are very early in the

development stage, publicly-funded researchers often opt for exclusive licenses, hoping to recoup higher returns on their investment. However, without proper checks and balances in the license agreements, this exclusivity may inhibit access.[132]

Open models of innovation, which are generally patent free and often rely on quick, straightforward licensing, have been successful, particularly in the early phase of biomedical research. In this model, partners work collaboratively, driving new fields of science and expanding the knowledge base for all, thereby hastening progress towards the development of medical tools. Such partnerships can be between and among industry partners or as part of public-private partnerships. Collaborating on precompetitive activities, for example, can help solve thorny technical challenges, better understand the aetiology of disease, validate potential novel medicine targets or identify biomarkers to ascertain if a health technology is working. This open model is especially important to lower the hurdles of entry and accelerate the pace of development of health technologies, including those needed to combat emergent diseases.[133]

Health technologies developed with public funds at universities can be lifesaving for individuals and populations far removed from the academic institutions in which they were invented. In many instances, public funds are used to support clinical trials, comparative effectiveness trials or trials undertaken during global health emergencies. This public support is vital to tackling the health needs of populations and is strongly encouraged. However, concerns often arise that the public pays twice: first through taxpayer support for research and then when purchasing the resulting health technologies at escalating prices.[134]

For the public to reap the full benefit of the public investment in research, public funding agencies must ensure that, when feasible, data, results and knowledge generated from such public investment be made broadly available. Such availability might be achieved, for example, through strong, enforceable policies on data sharing and data access that are a condition of grant awards, by creating data repositories and by establishing normative data standards that can be adopted and used by the biomedical community. In all cases, public funding agencies should strongly encourage patenting and licensing practices that benefit public health, including the use of non-exclusive licences, donation of intellectual property rights, participation in public sector patent pools and other mechanisms that can maximize innovation while promoting access.

In the context of licensees with implications for resource-limited settings, public health-sensitive provisions for the management of intellectual property deriving from publicly-funded research (sometimes referred to as global access licensing provisions) can be pursued. Over the past two decades, some universities and public funding institutions have begun to explore and put such provisions and frameworks into place.[135] These provisions seek to promote technology transfer and access by requiring differentiated licensing terms and conditions according to a number of factors such as geography, income, manufacturing and distribution costs, among others.

2.6 Recommendations

2.6.1. TRIPS flexibilities and TRIPS-plus provisions

World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. More specifically:

(a) WTO Members must make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred.

  (i) The United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should cooperate with one another and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.

  (ii) These multilateral organizations should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

(b) Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.

(c) WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

(d) Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be formally reported to the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.

(e) Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.

2.6.2 Publicly-funded research

(a) Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research.

(b) Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices. Such practices may include publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others. Sufficient incentives must be in place in these practices to make it attractive for developers to underwrite the cost of bringing a product to market at affordable prices that ensure broad availability.

(c) Universities and research institutions that receive public funding should adopt policies and approaches that catalyse innovation and create flexible models of collaboration that advance biomedical research and generate knowledge for the benefit of the public.

3. NEW INCENTIVES FOR RESEARCH AND DEVELOPMENT OF HEALTH TECHNOLOGIES

Market-driven R&D has been credited by some for producing a number of important health technologies that have improved health outcomes significantly throughout the world. But serious gaps, both in innovation and access, persist. Under the prevailing model, the biomedical industry, with the help of well-established intellectual property protection mechanisms, test data exclusivity and significant public funding of research, invests in R&D, obtains marketing approval and pays for related expenses by charging prices that allow them to recover these substantial costs and generate a profit. Shareholders who invest in biomedical companies do so with the expectation of generating a return on investment.

While this system has resulted in innovative products coming to the market, it also has created important tensions because of high prices, and fuelled policy incoherencies through the application of exclusivity-driven business models. Because this system is predicated on the ability to generate profit, governments and the biomedical industry have often failed to deliver new health technologies for diseases that do not, and cannot, promise high returns—those that mostly afflict the poor regardless of where they may live.[136]

Antimicrobial resistance is a global public health threat, whose impact and proportions have the potential to kill millions of people. Yet, AMR represents a fundamental commercial dilemma for private sector companies: developing new antibiotics is often an expensive, long-term proposition. The resulting medicines, to retain their power and effectiveness, must be used judiciously and for a limited time, which limits the market potential and curtails profits. The private, public and non-profit sectors all concur that the market will not solve this problem and that special interventions to address this situation need to be enacted.[137]

In contrast, R&D funding for rare diseases, once largely forgotten because of the low returns on investment that results from the small number of people afflicted, is increasing. This is due to several factors: advances in technology, particularly for genetically-linked diseases, and strong pressure and funding from patient advocacy groups. This is accompanied by the realization by private sector companies of the significant profit potential that rare disease treatments can have, particularly in wealthier countries.[138]

Various efforts are being undertaken by governments, international organizations, the private sector, philanthropic organizations and civil society to promote R&D for unmet health needs. However, the absence of a robust priority-setting mechanism for health R&D has exacerbated policy incoherencies. Naturally, public funders of health R&D are established under national laws and are accountable to national governments. Therefore, they are not held accountable by the international community for failing to prioritize global health needs.[139]

3.1 Delinking the costs of research and development from the end product

There are numerous mechanisms and tools now in use that provide new incentives for health technology innovation.[140] Some of these have been around for many years and are discussed, for instance, in the 2006 report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health.[141] What many have in common is that they incorporate aspects of delinkage. These mechanisms fall into several categories, which often intersect, including the following:

- **Push** mechanisms are upfront grants and in-kind contributions that get a project off the ground and into the market by mitigating the prohibitive costs of R&D or its most expensive parts, such as Phase III clinical trials.
- **Pull** mechanisms promise financial rewards after an objective or milestone has been reached. Rewards may include incentives, such as tax breaks, prizes or so-called advance market commitments, by which procurers commit to buy a certain amount of medicines or vaccines from a producer.[142]
- **Pooling** aggregates funding, data and intellectual property or related proprietary information to facilitate sharing of data and expertise for production of the final products.
- **Open collaborative research** platforms, like the Open Source Drug Discovery consortium, enable researchers from various disciplines and countries to work together to solve complex challenges encountered during upstream research.
- **Public-private partnerships and product development partnerships**, which may be funded by some of the delinkage mechanisms described above, synergize both the resources and strengths of the private and public sectors.[143] By eliminating or significantly limiting exclusivities, PDPs can make their products widely available as global public goods.

Philanthropies and governments generally provide around 90% of PDP funding.[144] Prominent global health and development organizations, together with industry partners, adopted the London Declaration on Neglected Tropical Diseases in 2012, with the aim of expanding R&D partnerships and monitoring progress towards NTD eradication by 2020.[145] In 2014, most global funding of R&D for neglected disease research went directly to researchers (72%) with around 22% (or US$ 526 million) going to PDPs.[146] The two largest philanthropic investors—the Bill and Melinda Gates Foundation and the Wellcome Trust—together contributed US$ 660 million on R&D in NTDs in 2014.[147] A number of other funds have been established in recent years to support R&D for health technologies to address neglected areas,[148] and these commitments are helping revitalize health technology innovation in these areas.

In January 2016, representatives of the pharmaceutical, biotechnology and diagnostics industries adopted a Declaration on Combating Antimicrobial Resistance. The declaration, adopted by almost 100 companies and 11 industry associations as of the end of June 2016, commits signatories to increasing investment in R&D by extending collaborative initiatives between industry, academia and public bodies to increase and improve research into new antibiotics, diagnostics, vaccines and other alternative treatments.[149] As important as these efforts may be, the fact remains that the production of health technologies for many diseases is far from sufficient and current efforts do not offer enough long-term, sustainable solutions.[150]

WHO has taken leadership with its Global Action Plan on Antimicrobial Resistance (GAP-AMR), which combines new medicine discovery, development and stewardship.[151] The WHO Global Antibiotic Research and Development Partnership (GARD)—formed with the Drugs for Neglected Diseases initiative (DNDi) and engaging industry, PDPs, academia, civil society and national health authorities from countries of all income levels—is a promising initiative to develop new antibiotics which are suitable for resource-limited settings.[152] Political commitment is important to ensure that this nascent partnership is adequately resourced. The European Union's Innovative Medicines Initiative is working on economic stimulants for antibiotics R&D.[153]

These efforts are characterized by an understanding that global challenges, such as AMR, require multifaceted approaches and multilateral planning and coordination.[154] For this, the three mechanisms that can be used to implement delinkage as outlined by the WHO Global Strategy and Plan of Action (2008) are: priority setting, financing and coordination.[155]

In spite of encouraging signs, many are pessimistic that this miscellany of new approaches will never be equal to the needs left unfulfiled by the market model. Consensus and demand are growing for a coordinated global R&D agenda, buttressed by solid financial commitments from governments. Significant work has been done toward this goal, as set forth in the WHO Global Strategy and Plan of Action and the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). While the CEWG work plan continues to be discussed at consecutive World Health Assemblies, progress is slow given the immediacy of the challenge.[156]

3.2 Priority setting and coordination

The 2030 Agenda stresses the need for "quality, accessible, timely and reliable disaggregated data" to measure progress, inform decision-making and ensure that no one is left behind.[157] There is wide agreement on the importance of comprehensive and accurate models and "metrics for evaluating performance, setting targets, guiding the distribution of scarce health resources and advancing access to affordable medicines."[158] Toward this end, the WHO Global Observatory on Health Research and Development, still in pilot stage, aims to provide a centralized and comprehensive source of data from diverse sources on what health R&D is being conducted globally, where it is being conducted, by whom and how. One of the Observatory's goals is to identify R&D gaps and opportunities and define priorities for new R&D investments.[159]

An example of such priority setting is the WHO R&D Blueprint, an initiative of preparedness and response to emerging pathogens that could cause severe outbreaks but for which there are no medical countermeasures.[160] However, the Blueprint has only been used once—during the 2014-2015 Ebola outbreak, after which the United Nations Secretary-General established a High-Level Panel on Global Response to Health Crises. The robustness and replicability of the WHO R&D Blueprint has yet to be assessed.

Among its findings, that High-Level Panel noted that the "high risk of major health crises is widely underestimated, and that the world's preparedness and capacity to respond is woefully insufficient." [161] R&D on emerging infectious diseases can be considered critical to the welfare of nations as well as for cross-border security that it should be considered a part of national security budgets.[162] Analysis of the temporal pattern of emerging infectious disease (EID) events over the last six decades predicts the emergence of five new EIDs each year if no mitigation policies are adopted now.[163]

But how will all of this be paid for? Recent EID events offer a stark reminder of the need for delinkage. Prior to 2014, Ebola outbreaks were primarily confined to remote regions of West Africa, where the majority of residents live on less than a dollar a day.[164] Prior to 2015, Zika was an obscure virus that received little attention from the global community.[165] No one expected either virus to leave its endemic borders or spread so rapidly. Consequently, no vaccines were developed. Promising Ebola therapies languished in preclinical R&D for over ten years without funding.[166] Rapid point-of-care diagnostics could have protected health workers in the 2014-2015 Ebola outbreak, eased overburdened treatment centres and reduced patient loss to follow-up.[167] Instead, a reported 11,310 of the 28,652 people infected died.[168]

3.3 Financing

Ideas for collaborative health-related R&D and alternative patent and licensing structures and financing mechanisms abound, but stakeholders are now calling for action. "An absolutely necessary condition for implementing [delinked R&D] approaches will be a sustainable source of funding," the CEWG noted in its 2012 report.[169] Where will the financing to turn ideas into action come from? Greater public financial commitments—and accountability for those commitments—are necessary.[170] At present, the major share of global biomedical R&D is concentrated in the United States, European countries and Japan.

While the major share of health technology R&D financing is borne by the private sector, untapped opportunities for

increasing private sector funding still exist. The final report of the United Kingdom Government-convened 'Review on Antimicrobial Resistance' contains a proposal calling on governments to consider a small levy on the pharmaceutical sector. This proposal merits careful consideration by governments as one way to increase funding for market entry rewards for new antibiotics.[171] Initiatives by governments, the private sector and non-government actors to incentivize upstream research should also be carefully considered.

A much greater funding responsibility, however, must be shouldered by governments, as they bear responsibility to their citizens to progressively realize the highest attainable standard of health. The report of the Review on AMR, for example, calls for a Global Innovation Fund of up to US$ 2 billion over five years to incentivize the development of new antibiotics and other unmet health needs.[172] Other initiatives awaiting funding by governments include a proposal for a Health Product R&D Fund discussed in a recent report of the Special Programme for Research and Training in Tropical Diseases (TDR)[173] and the so-called "demonstration projects" approved by the World Health Assembly to demonstrate effectiveness of new, innovative and sustainable financing and coordination approaches to address identified R&D gaps.[174]

Four years ago, the CEWG recommended that the United Nations set targets, based on Gross Domestic Product, for government funding of health-related R&D. This would involve both national spending and commit wealthier countries to help poorer ones. The CEWG proposed a binding R&D treaty or convention to hold governments to those commitments. While that proposal has increasingly gathered support, negotiations at WHO are proceeding slowly.[175]

Considering the limits to financing public health R&D through domestic taxation, private philanthropy and official development assistance, innovative sources of financing, such as taxes on global transactions, have the potential to overcome this constraint. Progress has been made in recent years, for instance, through the leadership of the Leading Group.[176] As affirmed in the Addis Ababa Action Agenda on Financing for Development, more countries should join in the effort to develop and implement new and innovative sources of financing public R&D.[177] All these, as well as new opportunities and, if necessary, alternative forums should be explored.

To resolve incoherence between market exclusivity-driven approaches and policies that steer investment and attention to where they are most needed, some current initiatives should be scaled up and other new ones created. The obligation of governments to uphold the right to health is not conditional on the availability of effective R&D mechanisms. Governments must therefore lead the private sector, civil society and other stakeholders in building coordinated public health R&D systems and financing them equitably, accountably and sustainably.

Box 9: The case of antimicrobial resistance

AMR is one of the most crucial health problems facing the world today. New models of R&D are under consideration and delinkage may provide the most useful path forward to address AMR. A successful strategy requires as a minimum global coordination and prioritization, sustainable and predictable funding for R&D from basic research through set stages of clinical development, collaboration between and among government, academia and the private sector, management of intellectual property, regulatory convergence, manufacturing capacity, implementation of surveillance and preservation mechanisms and education.

The High-Level Panel recognizes the trailblazing work of recent reviews, commissions and the unprecedented high-level meeting at the United Nations on AMR. The High-Level Panel also recognizes that it is imperative to sustain and enhance this momentum and recommends the establishment of an independent international committee responsible for assessing, coordinating and mapping R&D developments in this field. This international committee should also be charged with assisting in resource mobilization and ensuring the efficient allocation and use of funds so that antimicrobial medicines and point-of-care diagnostics will be available and accessible to those most in need.

Such an international committee should be charged by the United Nations to provide policy, regulatory and institutional direction on the issue of AMR, working in partnership with WHO and the various public and private sector initiatives directed at addressing the urgent need for the development of new tools. The High-Level Panel emphasizes that market-based models of innovation for AMR are unsustainable. Funding for R&D to address AMR and related challenges must be operationalized through delinkage models. Indeed, the challenge of AMR represents an important and incontestable context in which the viability of delinkage innovation models can be fully explored.

3.4 Recommendations

(a) It is imperative that governments increase their current levels of investment in health technology innovation to address unmet needs.

(b) Stakeholders, including governments, the biomedical industry, institutional funders of healthcare and civil society, should test and implement new and additional models for financing and rewarding public health research and development (R&D), such as the transaction taxes and other innovative financing mechanisms.

(c) Building on current discussions at the WHO, the United Nations Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and

development from end prices to promote access to good health for all. Such a Convention should focus on public health needs, including but not limited to, innovation for neglected tropical diseases and antimicrobial resistance and must complement existing mechanisms.

(d) As a preparatory step, governments should form a Working Group to begin negotiating a Code of Principles for Biomedical R&D. The Principles would apply to public R&D funds and should also be adopted by private and philanthropic funders, product development partnerships, universities, the biomedical industry and other stakeholders. Governments should report annually on their progress in negotiating and implementing a Code of Principles as a preparatory step to negotiating the Convention in the United Nations General Assembly.

4. GOVERNANCE, ACCOUNTABILITY AND TRANSPARENCY

Good governance,[178] accountability, stakeholder participation and transparency are decisive enablers and part and parcel of the 2030 Agenda.[179] The rules governing human rights, trade and public health exist in separate but overlapping spheres; their implementation rests at different levels. An important factor behind the incoherence between trade, intellectual property laws, human rights and public health lies in the different accountability mechanisms and uneven levels of transparency.

Human rights place a legal obligation on governments to progressively realize the right to health. Yet, in the context of health technologies, trade and investment agreements regularly contain TRIPS-plus provisions that increase levels of intellectual property protection and enforcement that impede the ability of governments to use laws and policies promoting their human rights obligations to the fullest extent possible. Trade and intellectual property-related accountability mechanisms are typically regulated by the WTO Dispute Settlement Understanding and the relevant dispute settlement provisions within a free trade agreement or related treaty. On the other hand, existing human rights accountability mechanisms are characterized by varying degrees of precision, legal weight and enforceability.[180]

Transparency is a core component of good governance. Civil society and patient groups rely on transparency of information to hold government authorities, private sector companies and international organizations accountable. Transparency can ensure fairness during negotiations that take place between biomedical companies and procurement organizations. The work of regulatory authorities in enhancing both innovation and access could be significantly aided if accurate information on the costs of R&D, production and distribution of health technologies were available. Most regulatory authorities already mandate the disclosure of information on quality, safety and efficacy of health technologies and some encourage information sharing on investments made in the R&D of health technologies. However, this information can be difficult to disaggregate.

Another area heavily affected by the lack of transparency and stakeholder participation is the negotiation and setting of trade rules. Human rights treaties, United Nations General Assembly and Security Council resolutions, various public health and human development commitments, like the SDGs, are debated, negotiated and committed to publicly. While the principles of the WTO require that negotiations should be transparent,[181] in practice and in other forums, trade and investment agreements are often negotiated in secrecy. The lack of transparency in trade negotiations typically limits the ability of civil society, patient groups, labour unions, consumer associations, health professionals and even parliamentarians to assess the human rights and public health impacts and to hold governments accountable. Any robust and effective accountability framework for improving innovation and access to health technologies requires coherence and coordination across sectors and multiple layers of oversight, including in the political, administrative, legal and social realms. The framework must be grounded in human rights and all stakeholders—especially patient representatives, civil society and parliamentarians—must be enabled, supported and legally protected to effectively participate at every stage.

4.1 Governance and accountability

Multilateral organizations, governments, the private sector and civil society all have a critical role to play in governance and accountability for innovation and access to health technologies, including with regard to increasing transparency.

4.1.1 International and multilateral organizations and governance and accountability

Policy incoherencies among human rights, trade and public health are echoed in the United Nations and in the related organizations that support Member States to address these issues.[182] Many international organizations and United Nations entities that work on issues of health technology innovation and access operate under differing governance structures with different mandates that makes collaboration and coherence challenging.[183] The activities undertaken by these organizations and the policy advice they provide to governments and other stakeholders in accordance with their mandates can often amplify the incoherencies between human rights, trade rules and public health objectives.[184]

WHO, WIPO and WTO have strengthened their collaboration on health technology innovation and access in recent years, but do not necessarily take into account or align with the work of the Office of the United Nations High Commission for Human Rights (OHCHR), the United Nations Industrial Development Organization (UNIDO) the Joint United Nations Programme on HIV/AIDS (UNAIDS) or UNDP. Mechanisms such as interagency working groups can help to improve coordination between the different agencies and ensure greater coherence in the advice and support to governments and other stakeholders. Precedents exist for improving collaboration and coordination through interagency entities such as the United Nations Development Group, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the recently established United Nations Interagency Task Force on the Prevention and Control of Noncommunicable Diseases.[185]

The 2030 Agenda calls for "robust, voluntary, effective, participatory, transparent and integrated" mechanisms of "follow-up and review" of Member State progress toward the SDGs.[186] This requires that reporting mechanisms be put in place by governments to monitor progress and identify gaps in meeting requirements.

The Millennium Development Goals (MDG) Gap Task Force was established by the Secretary-General of the United Nations in 2007 to improve monitoring of the global commitments contained in MDG 8: 'Develop a Global Partnership for Development.'[187] One of the five core elements on which the taskforce systematically reported was health technology

innovation and access. However, the incoherencies between human rights, trade rules and public health were not addressed in the reports. The impact of the taskforce reports in influencing health technology innovation and access initiatives is unknown, largely because there were no accountability mechanisms attached to its reporting. In 2010, when progress was lagging on the health of women and children, the Secretary-General of the United Nations created a Commission on Information and Accountability for Women's and Children's Health to make recommendations on advancing progress. In turn, the Commission set up an Independent Expert Review Group to monitor and report on the degree to which states and non-state actors were implementing those recommendations.[188] The models could also be used for improving accountability for health technology innovation and access, including to follow up on this High-Level Panel's recommendations.

4.1.2 National governance, accountability and civil society

The effective drafting and implementation of national legislation to incentivize health technology innovation and the negotiation of trade agreements requires the participation of multiple government departments and ministries, whose mandates overlap and intersect. The most obvious of these are trade, commerce and industry, economic development, science and technology, health, justice, foreign affairs, finance and national planning. Countries ranging from Lesotho to Switzerland have improved domestic policy coherence by bringing representatives of several ministries together under an authoritative head in working groups on health technology innovation and access.[189] In most countries, however, these groups do not exist. Where they do, their functioning is usually ad hoc and beset by the asymmetries of influence that exist across most governments.[190]

An important tool to promote government accountability is independent 'shadow reporting' to United Nations bodies, which can help to highlight unaddressed issues, misinformation and/or problematic conduct.[191] But many of the stakeholders, such as civil society and patient groups who produce shadow reports, operate in an environment of dwindling financial resources, suppression of civil society activity and declining access to platforms where human rights, trade and public health rules are negotiated and monitored. They need adequate resources and space for shadow reports as well as to advocate for improving innovation and access to health technologies.[192]

Human rights and public health impact assessments are another important modality for holding governments accountable for their actions in negotiating and concluding trade agreements that may adversely impact the right to health. The fundamentals of human rights impact assessments are outlined in the United Nations Guiding Principles on Business and Human Rights, proposed by John Ruggie, the United Nations Special Representative for Business and Human Rights, and endorsed by the United Nations Human Rights Council in 2011.[193] Known as the 'Ruggie Principles,' these are guidelines for states and companies to prevent, address and remedy human rights abuses committed in business operations. Calls for human rights impact assessments of health technology innovation and access are gaining ground with experts in human rights, health and development.[194] The Ruggie Principles distinguish between a private business's responsibilities and a state's binding obligations and establish a hierarchy of three core principles: 1) the state duty to protect against human rights abuses by third parties, including businesses; 2) the corporate responsibility to respect human rights; and 3) the need for more effective access to remedies for failure to abide by these responsibilities.[195] In other words, governments are ultimately responsible for safeguarding human rights. Concomitantly, governments must apply "appropriate and effective remedies when [those laws are] breached." [196] Other UN and multilateral organizations and bodies have issued guidelines and clarifications on the obligations of businesses.[197] But those remedies largely remain to be enacted and enforced.

In June 2016, the CESCR released some important observations on the conduct of state parties when concluding trade agreements. The Committee urged state parties to the ICESCR to undertake consultations with relevant stakeholders, including engaging affected communities in the development stages of negotiation and ratification of trade agreements, based on an assessment of expected impacts, and to ensure that an impact assessment is systematically conducted during implementation to adapt, if necessary, the content of the commitments.[198] This important development signals a growing sense of government accountability to ensure that the consequences of trade-related commitments entered into are carefully considered and involve participation of key stakeholders, including civil society.

4.1.3 Corporate governance and accountability

Various voluntary and market-based mechanisms are set up to encourage greater accountability among corporations for innovation and access to health technologies, including greater public scrutiny. However, with monitoring and ranking mechanisms, such as the Access to Medicines Index, it is difficult to assess the effect of the rankings on company policies and practices.[199]

The Ruggie Principles call on companies to conduct "due diligence" to "identify, prevent, mitigate and account for how they address their adverse human rights impacts," redress their failures and publicize their remedial actions.[200] Some pharmaceutical companies do this and report on it as part of their annual reporting process.[201] The United Nations Global Compact on corporate social responsibility, currently signed by more than 8,902 companies in over 166 countries, encourages transparency through annual Communication on Progress reports on sustainability.[202] Voluntary corporate social responsibility, while laudable, is limited by the fact that any action taken by companies is exactly that—voluntary in nature.

4.2 Transparency

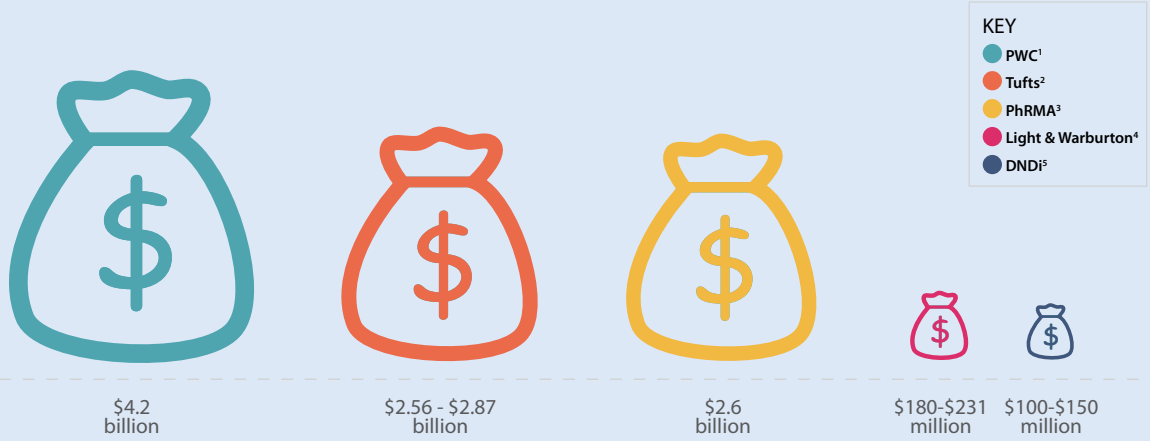
4.2.1 R&D costs and pricing of health technologies

To realize a fair public return for public investment, government actors and public funders should require clear information on what it costs to innovate and bring a particular health technology to market. Although publicly-traded companies are legally required to disclose a range of financial information in their annual report, privately held ones are not, and even when disclosed, the data can be incomplete and difficult to parse and may not be sufficiently disaggregated, for example between R&D costs and marketing costs. For instance, R&D costs are not broken down by product, nor are precise sources of income listed in many cases, so a research grant from a government agency may not appear in a grantee's books depending on accounting practices and the levels of funding involved.[203] Ultimately, cost estimates vary widely depending on the source.

For instance, a 2016 study conducted by the industry-funded Tufts Centre for the Study of Drug Development pegged the average total cost of bringing a new medicine to market at US$ 2.56 billion to US$ 2.87 billion.[204] Although often cited, this is a deeply contested figure.[205] In comparison, the non-profit DNDi analyzed its own R&D costs and found that it spent US$ 39 million to US$ 52 million developing a new chemical entity. Adjusting for the risk of failure, as originator companies usually do, the number from DNDi rose to US$ 130 million to US$ 195 million.[206] Of course, this cannot be taken as a direct comparison, given the significant disparities in R&D costs depending on the health technologies in question and the costs of operation. However, it does provide a window into the very large disparities that exist in R&D cost estimates. Marketing cost estimates show similar disparities. Industry authorities generally claim more is spent on R&D than on marketing, but an analysis by Canadian academics concluded the opposite.[207] More complete disclosure is needed to create reliable data on costs of health technology research, development and marketing. At present, this important information is scattered over numerous conflicting sources and much is missing.

Some public databases of medicine, vaccine, diagnostic and medical device prices exist. The WHO Global Price Reporting Mechanism (GPRM), for instance, records international transactions (volumes, prices, terms and other information) of HIV, tuberculosis and malaria medicines and diagnostics purchased by national programmes in low- and middle-income countries, as do other international organizations and governments.[208] The Vaccine Product, Price and Procurement web platform (V3P), another WHO initiative, provides information on vaccine product, price and procurement data.[209] Non-governmental organizations, such as Médecins Sans Frontières and Health Action International, have kept databases and produced publications to track the prices of key health technologies.[210] These mechanisms have strengths, but also limitations—such as the surveying of only some countries and some diseases. Furthermore, many complexities get in the way of confirming prices. Discounts, mark-ups, taxes and regional differences mean that prices vary within countries and final prices may not match list and factory prices.[211] Even in relatively transparent systems, published lists do not

R&D costs – a wide range of estimates



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always disclose pricing arrangements between suppliers and public procurers.[212] Timely, comprehensive and user-friendly databases on costs and prices are needed.

4.2.2 Clinical trials

Healthcare providers need complete, up-to-date clinical trial data to give patients the safest, best treatments. A 2013 United Kingdom parliamentary committee pointed out the serious problem of lack of information sharing from clinical trials: "Important information about clinical trials is routinely and legally withheld from doctors and researchers by manufacturers. This longstanding regulatory and cultural failure impacts on all of medicine and undermines the ability of clinicians, researchers and patients to make informed decisions about which treatment is best." [213]

Clinical trials are required by regulatory authorities before approval is given to manufacturers to enter the market and are meant to assure the safety and efficacy of health-related products. Clinical trials are also the biggest R&D expense.[214] Increased transparency of clinical trial information is an important contributor to improved public health outcomes. Secondary and meta-analyses may change clinical practices and reveal that interventions are ineffective or unsafe, as happened in the case of selective serotonin reuptake inhibitors antidepressants.[215] When baseline data is published on trial subjects' ages, gender and health conditions (while protecting patient confidentiality) doctors and health authorities can gauge the merits of a treatment for people with similar characteristics.

Clinical trial sponsors and scientists are guided by a patchwork of national laws and non-binding professional ethical standards for research involving human subjects.[216] But trials are not only conducted in the country where the product is discovered or developed and the health technologies are used around the world. A lack of coordination between national drug regulatory authorities can also delay registration of new heath technologies. Government regulators do not always enforce their own rules stringently.[217]

Transparency of clinical trials is not always a given. The initiators of trials commonly require non-disclosure agreements, in which the institutions that conduct the trials consent to keep the protocols, patient data and research results secret.[218] Some conductors of clinical trials have introduced bias into study designs and suppressed negative results,[219] although this does not appear to be common practice. To address the need for global transparency, several years ago WHO established the International Clinical Trials Registry Platform (ICTRP) that can serve as a single database where voluntarily-provided trial data can be made available. However, the ICTRP does not yet include any trial results, although work is underway to do so.[220] In 2014, the European Medicines Agency adopted a new policy to make clinical studies available.[221]

4.2.3 Patent information

Transparent patent information can be an important a determinant of health outcomes. When the status and details of intellectual property protections are easily accessible, competitors can confidently release cheaper health technologies similar to out-of-patent products.[222] Also, governments, generic companies, researchers and civil society can more easily review and oppose questionable patent applications and grants and monitor whether officials are applying patentability criteria as required by national laws.

Currently, patent information is often confusing, incomplete and fragmented. A single product may be protected by hundreds of patents[223] and compounds may appear under a brand name or an international non-proprietary name (INN). Patents pile up over time, with no indication as to which ones the holder plans to enforce[224] and extend. These factors, as well as excessive patenting, can impede scientific progress and legitimate competition.[225]

Multilateral organizations, such as WHO, WIPO and WTO, provide support to countries and procurement agents to navigate the mazes of patent information needed to make procurement decisions.[226] A number of countries and organizations publish patent databases and conduct surveys and analysis (referred to as "patent landscapes") covering certain fields of health technologies and groups of essential medicines, such as ARVs.[227] These efforts begin the process of creating a comprehensive source of global patent information—but like the data itself, they are still incomplete and scattered.

4.3 Recommendations

4.3.1 Governments

(a) Governments must review the situation of access to health technologies in their countries in light of human rights principles and States' obligations to fulfil them, with assistance from the Office of the United Nations High Commissioner for Human Rights (OHCHR) and other relevant United Nations entities. The results of these assessments should be made publicly available. Civil society should be financially supported to submit their own shadow reports on innovation and access to health technologies. Such national reviews should be repeated at regular intervals.

(b) Governments should strengthen national level policy and institutional coherence between trade and intellectual property, the right to health and public health objectives by establishing national inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access. Appropriate member/s of the national executive who can manage competing priorities, mandates and interests should convene such bodies. The deliberations and decisions of such groups should operate with a maximum of transparency. Civil society should be financially supported to participate and submit their shadow reports on innovation and access to health technologies.

4.3.2 Multilateral organizations

(a) The United Nations Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access. Challenges and progress on innovation and access to health technologies under the ambit of the 2030 Agenda, as well as progress made in implementing the recommendations of this High-Level Panel, should be monitored by this body. Membership should comprise of representatives from United Nations and multilateral organizations, civil society, governments, academia and the private sector.

(b) The United Nations Secretary-General should establish an inter-agency taskforce on health technology innovation and access. This taskforce, operating for the duration of the SDGs, should work toward increasing coherence among United Nations entities and relevant multilateral organizations like the WTO. The taskforce, also charged with overseeing the implementation of the High-Level Panel's recommendations, should be coordinated by the United Nations Development Group and report annually to the United Nations Secretary-General on progress made in enhancing United Nations system-wide coherence.

(c) The United Nations General Assembly should convene a Special Session no later than 2018 on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access as set out in the 2030 Agenda. Civil society should be financially supported to participate and submit their reports on innovation and access to health technologies at this Special Session.

4.3.3 Private sector companies

(a) Biomedical private sector companies involved in health technology innovation and access should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.

(b) Private sector companies should implement the following:

(i) a publicly available policy on their contribution to improving access to health technologies setting out general and specific objectives, timeframes, reporting procedures and lines of accountability; and

(ii) a governance system that includes direct board-level responsibility and accountability on improving access to health technologies.

4.3.4 R&D, production, pricing and distribution of health technologies

(a) Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to:

(i) The costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and

(ii) Any public funding received in the development of the health technology, including tax credits, subsidies and grants.

(b) Building on the Global Price Reporting Mechanism (GPRM), V3P and others, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.

4.3.5 Clinical trials

(a) Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the WHO Clinical Trials Registry Platform, clinicaltrials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.

(b) To facilitate open collaboration, reconstruction and reinvestigation of failures, governments should require that study designs and protocols, data sets, test results and anonymity-protected patient data be available to the public in a timely and accessible fashion. Those undertaking clinical trials must not prevent researchers from publishing their findings.

4.3.6 Patent information

(a) Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include:

- standard international common names for biological products;
- international non-proprietary names for products, either as known at the time of application or after the granting of a patent; and
- dates of grant and expiry.

END NOTES

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[47] United Nations Committee on Economic, Social and Cultural Rights, General Comment 14: The right to the highest attainable standard of health (Art. 12), UN Doc. E/C.12/2000/4 (2000). It should be noted that the General Comment refers to both "essential medicines" as defined from time-to-time by the WHO as part of the "minimum core obligation" of states, but also refers repeatedly elsewhere, outside the context of minimum core obligations, to essential medicines without adding this limiting reference — and in the most recent resolution on the matter from the United Nations Human Rights Council (albeit one adopted without consensus, on a vote with some abstentions but no outright opposition), Member States themselves have confirmed that the right to access to medicines extends beyond just "essential" medicines: Human Rights Council, "Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," Resolution 23/14, UN Doc. A/HRC/23/L.10/Rev.1 (June 11, 2013).

[48] Human Rights Council (2013) Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/23/L.10/Rev.1. Available from: http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_en.pdf [Accessed 8 August 2016], para. 5-10.

[49] Constitution of the WHO, entered into force 7 April 1948. Available from: http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1 [Accessed 8 August 2016], preamble.

[50] See, e.g., Marks, S. (2009) Access to essential medicines as a component of the right to health, in: Clapham, A. and Robinson, M. (eds.) *Realizing the right to health*. Zurich, Switzerland: Rüfer and Rub, pp. 82-101.

[51] Hunt, P. (2006) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/61/338. Available from: https://documents-dds-ny.un.org/doc/UNDOC/GEN/N06/519/97/pdf/N0651997.pdf?OpenElement [Accessed 13 July 2016].

[52] See Grover, A. (2009) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/11/12, para. 108. Available from: http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf [Accessed 3 August 2016].

[53] ICESCR, entered into force 3 January 1976, Art. 2. Available from: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx [Accessed 24 May 2016]. See also: Pūras, D. (2015) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/29/33, para. 19. Available from: http://www.ohchr.org/EN/Issues/Health/Pages/AnnualReports.aspx [Accessed 15 July 2016].

[54] Ruggie, J. (2009) Report of the Special Representative of the Secretary-General of the United Nations on the issue of human rights and transnational corporations and other business enterprises, A/HRC/11/13/Add.1. Available from: https://documents-dds-ny.un.org/doc/UNDOC/GEN/G09/133/98/pdf/G0913398.pdf?OpenElement [Accessed 13 July 2016].

[55] Sub-Commission on the Promotion and Protection of Human Rights (2003) Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights, E/CN.4/Sub.2/2003/12/Rev.2. Available from: https://documents-dds-ny.un.org/doc/UNDOC/GEN/G03/160/08/pdf/G0316008.pdf?OpenElement [Accessed 13 July 2016]. See also: CESCR (2000) General Comment No. 14: The right to the highest attainable standard of health (Art. 12), E/C.12/2000/4, para. 42. Available from: http://www.refworld.org/docid/4538838d0.html [Accessed 13 July 2016].

[56] UDHR (1948) A/810 at 71, Art. 27(2). Available from: http://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf [Accessed 8 August 2016]; ICESCR, entered into force 3 January 1976. Available from: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx [Accessed 24 May 2016].

[57] ICESCR (2005) General Comment No. 17: The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1(c), of the Covenant), E/C.12/GC/17, paras. 1-3. Available from: http://www.refworld.org/docid/441543594.html [Accessed 8 August 2016]. The Committee specifically notes (para. 2, fn. 1) that "relevant international agreements" to which it is referring include the WTO TRIPS Agreement and other international treaties on various aspects of intellectual property.

[58] Baker, B. and Avafia, T. (2011) The evolution of IPRs from humble beginnings to the modern day TRIPS-plus era: Implications for treatment access. Working Paper prepared for the Third Meeting

of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011. *Global Commission on HIV and the Law* [online]. Available from: http://www.hivlawcommission.org/index.php/working-papers?task=document.viewdoc&id=101 [Accessed 7 June 2016].

[59] Baker, B. and Avafia, T. (2011) The evolution of IPRs from humble beginnings to the modern day TRIPS-plus era: Implications for treatment access. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011. *Global Commission on HIV and the Law* [online]. Available from: http://www.hivlawcommission.org/index.php/working-papers?task=document.viewdoc&id=101 [Accessed 7 June 2016].

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[61] Pūras, D. (2015) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/29/33, para. 19. Available from: http://www.ohchr.org/EN/Issues/Health/Pages/AnnualReports.aspx [Accessed 15 July 2016]. See also: United Nations General Assembly Report General Assembly (2015) Report of the Special Rapporteur in the field of cultural rights, A/70/279, paras. 89, 90. Available from: http://www.un.org/en/ga/search/view_doc.asp?symbol=A/70/279 [Accessed 8 August 2016].

[62] Under a compulsory license, the state denies the patent-holder control but not remuneration—it pays a royalty.

[63] UNAIDS (2011) TRIPS flexibilities and access to antiretroviral therapy: Lessons from the past, opportunities for the future. *UNAIDS* [online] Available from: http://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA%2B10TRIPS_en_0.pdf [Accessed 20 June 2016]; Musungu, S. and Oh, C. (2005) The use of flexibilities In TRIPS by developing countries: Can they promote access to medicines? Study 4C: *Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)* [online]. Available from: http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf [Accessed 20 June 2016]. See also: Chaves, G. and Oliveira, M. (2007) A proposal for measuring the degree of public health-sensitivity of patent legislation in the context of the WTO TRIPS Agreement. *Bulletin of the World Health Organization,* 85(1), p. 50.

[64] Skyes, A. (2002) TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution" *John M. Olin Program in Law and Economics* Working Paper No. 140 [online]. Available from http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1596&context=law_and_economics [Accessed 2 August 2016]. See also Matthews D (2002) *Globalising intellectual property rights: The TRIPS agreement.* 1st ed. London: Routledge.

[65] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, adopted on 14th November 2001. *WHO* [Online]. Available from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [Accessed 8 August 2016]. See also: UNDP (2010) Good practice guide: Improving access to treatment by utilizing public health flexibilities in the WTO TRIPS Agreement. *WHO* [online]. Available from: http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf [Accessed 3 June 2016]; UNAIDS, WHO and UNDP (2011) Using TRIPS flexibilities to improve access to HIV treatment. Policy Brief. *UNAIDS, WHO and UNDP* [online] Available from: http://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf [Accessed 3 June 2016]; WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO, WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016].

[66] Abud, M.J., *et al*. (2015) An empirical analysis of primary and secondary pharmaceutical patents in Chile. *PLoS ONE,* 10(4): e0124257.

[67] Bouchard, R., *et al*. (2010) Empirical analysis of drug approval-drug patenting linkage for high value pharmaceuticals. *Northwestern Journal of Technology and Intellectual Property,* 8(2), pp. 174-227.

[68] Shaffer, E. and Brenner, J. (2009) A trade agreement's impact on access to generic drugs. *Health Affairs,* 28(5), pp. 957-968.

[69] UNITAID (2014) The Trans-Pacific Partnership Agreement: Implications for access to medicines and public health. *UNITAID* [online]. Available from: http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf [Accessed 27 June 2016]. See also: Sell, S. (2011) TRIPS was never enough: Vertical forum-shifting, FTAS, ACTA and TTP. *Journal of Intellectual Property Law*, 18(2), Art. 5; El-Said, H. and EL-Said, M. (2007) TRIPS-Plus implications for access to medicines in developing countries: Lessons from Jordan–United States Free Trade Agreement. *The Journal of World Intellectual Property*, 10(6), pp. 438-475.

[70] Under NAFTA provisions, for example, the United States biomedical company, Eli Lilly, is suing the government of Canada for US$ 500 million over invalidation of two of the innovator company's patents. *Eli Lilly and Company v The Government of Canada*, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (Nov. 7, 2012). Available from: http://italaw.com/sites/default/files/case-documents/italaw1172.pdf [Accessed 3 June 2016]. More at: http://www.italaw.com/cases/1625 [Accessed 3 June 2016]. For further discussion of the impact of "foreign investor privileges" on TRIPS-plus standards of intellectual property protection, see Baker, B. and Geddes, K. (2015) Corporate power unbound: Investor-state arbitration of IP monopolies on medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement. *Journal of Intellectual Property Law*, 23(1), Art. 2.

[71] Musungu, S., Villanueva, S. and Blasetti, R. (2004) Utilizing TRIPS flexibilities for public health protection through south-south regional frameworks. *South Centre* [online]. Available from: http://apps.who.int/medicinedocs/pdf/s4968e/s4968e.pdf [Accessed 23 June 2016].

[72] Contribution (100) from Safiatou Simpore Diaz, YOLSE, March 2016. Available from: https://highlevelpaneldevelopment.squarespace.com/inbox/2016/3/4/safiatou-simpore-diaz-english-translation [Accessed 23 June 2016].

[73] For a full discussion see Elliot, R. (2016) International legal norms: The right to health and the justifiable rights of inventors, Background paper prepared with the High-Level Panel Secretariat at UNDP in collaboration with UNAIDS. *UNDP*

[online]. Available from: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56da14af4d088e1b940103a4/1457132721678/DRAFT+Background+Paper+B.pdf [Accessed 7 June 2016].

[74] For example, when Thailand issued a compulsory licence on the antiretroviral medication *lopinavir/ritonavir* in 2007, the patent-holder withdrew all of its pending registration applications and announced it would not launch any new medicines in that country, thereby denying access to the heat-resistant form of lopinavir/ritonavir for which no generic equivalent existed. See: Wibulpolprasert, S., *et al.* (2011) Government use licences in Thailand: The power of evidence, civil movement and political leadership. *Globalization and Health,* 7(32); Yamabhai, I., *et al.* (2011) Government use licences in Thailand: An assessment of the health and economic impacts. *Globalization and Health,* 7(28); ITPC (2015) The campaign for use of compulsory licensing in Thailand. *Make Medicines Affordable* [online]. Available from: http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/ [Accessed 28 June 2016]; Reichman, J. (2009) Compulsory licensing of patented pharmaceutical inventions: Evaluating the options. *Journal of Law, Medicines and Ethics*, 37(2), pp. 247-263. The US Trade Representative (USTR) continues to put countries on its Special 301 watch list for using TRIPS flexibilities, in stark contrast to the Doha Declaration, which was universally agreed by all WTO Members (Office of the United States Trade Representative (2016) 2016 Special 301 Report. *Office of the United States Trade Representative* [online]. Available from: https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf [Accessed 3 June 2016].

[75] United Nations General Assembly (2015) Report of the Special Rapporteur in the field of cultural rights, A/70/279, para. 90 [online]. Available from: http://www.un.org/en/ga/search/view_doc.asp?symbol=A/70/279 [Accessed 30 June 2016].

[76] Art. 7 TRIPS Agreement states that *"[t]he 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."*

[77] The US Pharmaceutical Research and Manufacturers of America (PhRMA) for instance argues that intellectual property protections such as patents and data protection provide the incentives that spur research and development, ensuring that companies can secure the resources for future investments in research for the innovations of tomorrow. See: PhRMA (n.d.) Intellectual property protections are vital to continuing innovation in the biopharmaceutical industry. *PhRMA* [online]. Available from: http://www.phrma.org/innovation/intellectual-property [Accessed 3 June 2016].

[78] Grabowski, H. (2002) Patents, innovation and access to new pharmaceuticals. *Journal of International Economic Law,* 5(4), pp. 849-860.

[79] Blasi, A. (2012) An ethical dilemma: Patents & profits v. access & affordability. *Journal of Legal Medicine*, 33(1), pp.115-128.

[80] Commission on Intellectual Property Rights, Innovation and Public Health (2006) Public health, innovation and intellectual property rights. *WHO* [online]. Available from: http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1 [Accessed 2 June 2016], pp. 48-59.

[81] Reichman, J. and Hasenzahl, C. (2003) Non-voluntary licensing of patented inventions. Historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA. *ICTSD and UNCTAD* [online]. Available from: http://www.ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf [Accessed 15 July 2016], p. 20.

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[83] Lanjouw, J. (1998) The introduction of pharmaceutical product patents in India: "Heartless exploitation of the poor and suffering?" *National Bureau of Economic Research (NBER)* Working Paper No. 6366 [online]. Available from: http://www.nber.org/papers/w6366.pdf [Accessed 28 June 2016].

[84] In the United States for instance, the average retail price increase for 622 widely used medicines was more than six times higher than the rate of general inflation in 2013. Schondelmeyer, S. and Purvis, L. (2016) Rx Price Watch Report: Trends in retail prices of prescription drugs widely used by older Americans, 2006 to 2013. *AARP Public Policy Institute* [online]. Available from: http://www.aarp.org/content/dam/aarp/ppi/2016-02/RX-Price-Watch-Trends-in-Retail-Prices-Prescription-Drugs-Widely-Used-by-Older-Americans.pdf [Accessed 15 July 2016].

[85] Walker, J. (2015) Patients struggle with high drug prices. *The Wall Street Journal* [online]. December 31, 205. Available from: http://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981 [Accessed 2 August 2016]. For a comparison of out-of-pocket expenses burdens on consumers in OECD countries see: Kemp-Kasey, A. (2011) How much do we spend on prescription medicines? Out-of-pocket costs for patients in Australia and other OECD countries. *Australian health review: a publication of the Australian Hospital Association* 35(3):341-9.

[86] Experts in Chronic Myeloid Leukemia (2013) The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: From the perspective of a large group of CML experts. *Blood Journal*, 121(22), pp. 4439-4442.

[87] Across OCED countries, pharmaceutical spending reached around US$ 800 billion in 2013, amounting to 20% of total health spending on average when pharmaceutical consumption in hospitals is added to the purchase of pharmaceutical drugs in the retail sector. See OECD (2015) Health at a Glance 2015: OECD Indicators. *OECD* [online]. Available from: http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/health-at-a-glance-2015_health_glance-2015-en [Accessed 15 July 2016].

[88] For discussion of pros and cons of voluntary licences, see Park, C., *et al.* (2012) Understanding voluntary licensing: An analysis of current practices and key provisions in antiretroviral voluntary licences. *Medicines Patent Pool*, 2012 XIX International

AIDS Conference [online]. Available from: http://www.medicinespatentpool.org/wp-content/uploads/Current-Practice-and-Key-Provisions-in-ARV-VLs.pdf [Accessed 3 June 2016]; and Amin, T. (2007) Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines?. *I-MAK* [online]. Available from: http://static1.1.sqspcdn.com/static/f/129694/1099999/1192729231567/Oxfam+-+Voluntary+Licensing+Research+IMAK+We [Accessed 6 June 2016].

[89] According to its Executive Director, by mid-2015, the MPP's work had saved the international community US$ 119.6 million through the purchase of more affordable treatments. This is equivalent to one year of first-line treatment for approximately 950,000 people. Contribution (115) from Greg Perry, Medicines Patent Pool, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/28/greg-perry [Accessed 3 June 2016].

[90] The Medicines Patent Pool (2015) The Medicines Patent Pool expands mandate to hepatitis C and tuberculosis treatment. Available from: http://www.medicinespatentpool.org/the-medicines-patent-pool-expands-mandate-to-hepatitis-c-and-tuberculosis-treatment/ [Accessed 28 July 2016].

[91] For example, Merck's voluntary licence for paediatric formulations of *raltegravir* excluded countries like Algeria, Tunisia and China, despite having similar economies and disease burdens as countries covered by the licence. See De Luca, C. (2015) Medicine patent pool – pharma philanthropy or PR?. *Expert Opinion on Therapeutic Patents,* 25(11), pp. 1223-1227.

[92] The Gilead *sofosbuvir* license excludes China, Brazil, the Philippines, Turkey, Thailand, Mexico – middle-income countries home to 38.5 million hepatitis C infections (Hill, A., *et al.* (2016) Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C. *Journal of Virus Eradication*, 2, pp. 28-31).

[93] Art. 27.1 TRIPS Agreement.

[94] UNDP (2010) Good practice guide: Improving access to treatment by utilizing public health flexibilities in the WTO TRIPS Agreement. *UNDP* [online]. Available from: http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf [Accessed 3 June 2016].

[95] 35 U.S.C. § 100(b), 101, 120 (2006). For further discussion, see Kapczynski, A., *et al.* (2012) Polymorphs and prodrugs and salts (Oh My!): An empirical analysis of "secondary" pharmaceutical patents. *PLoS ONE*, 7(12), e49470.

[96] Such as India's Section 3(d) The Patents Act 1970. In 2013, in a globally impactful, seven-year case, India's Supreme Court upheld the patent office's rejection of a patent application on Novartis's cancer drug Gleevec under 3(d) (*Novartis AG v. Union of India & Ors.* [2013] Civil Appeal Nos. 2706-2716 of 2013. (Supreme Court of India), paras. 103, 131-133, 157, 190. In 2012, Argentina amended its patentability criteria essentially rejecting all secondary patents claims

[97] The Government of India, for instance, has faced increasing pressure to change its IP law-specifically section 3d on patentability criteria. For example in 2014, the US Government classified India as a "Priority watch list country" in the US Special 301 Report, based on the inputs provided by the US industry on their perception of the level of protection provided by India to Intellectual Property. See Ministry of Commerce and Industry (2014) US opposition to section 3(D) of the Indian Patent Act, press release. *Government of India* [online]. Available from: http://pib.nic.in/newsite/PrintRelease.aspx?relid=107612 [Accessed 6 August 2016].

[98] Kapczynski, A., *et al.* (2012) Polymorphs and prodrugs and salts (Oh My!): An empirical analysis of "secondary" pharmaceutical patents. *PLoS ONE,* 7(12), e49470; Committee on Development and Intellectual Property (CDIP) (2015) Study on pharmaceutical patents in Chile (CDIP/15/INF/2) *WIPO* [online]. Available from: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_15/cdip_15_inf_2.pdf [Accessed 7 June 2016], pp. 5-6.

[99] European Commission (2008) Pharmaceutical sector inquiry: Preliminary report. DG Competition Staff Working Paper. *European Commission* [online]. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [Accessed 28 June 2016], p. 10. See also: Abud, M.J., *et al.* (2015) An empirical analysis of primary and secondary pharmaceutical patents in Chile. *PLoS ONE*, 10(4), p. 2.

[100] Globerman, S. and Lybecker, K.M. (2014) The benefits of incremental innovation: focus on the pharmaceutical industry. *The Fraser Institute* [online]. Available from: https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf [Accessed 2 August 2016].

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[102] Intellectual Property Office UK (2011) Patent thickets. *Intellectual Property Office UK* [online). Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/312540/informatic-thickets.pdf [Accessed 6 June 2016], p. iii; European Commission (2008) Pharmaceutical sector inquiry: Preliminary report. *European Commission* [online]. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [Accessed 6 June 2016], p. 9.

[103] WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO and WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016], pp. 135-136.

[104] The lack of patent examination in South Africa results in a disproportionately high number of grants compared with other emerging economies (Correa, C. (2011) Pharmaceutical innovation, incremental patenting and compulsory licensing. *Centre for Interdisciplinary Studies of Industrial Property and Economics* [online]. Available from: http://idl-bnc.idrc.ca/dspace/bitstream/10625/47912/1/IDL-47912.pdf [Accessed 3 June 2016]). ICTSD, UNCTAD and WHO have also published guidelines (Correa, C. (2007) Guidelines for the examination of pharmaceutical patents: Developing a public health perspective. *WHO, ICTSD and UNCTAD* [online]. Available from: http://www.ictsd.org/sites/default/files/research/2008/06/correa_patentability20guidelines.pdf [Accessed 7 June 2016]). In 2016, UNDP published a more detailed and updated version of guidelines (Correa, C. (2016*)* Guidelines for the examination of patent applications relating to pharmaceuticals: Examining pharmaceutical patents from a public health perspective. *UNDP* [online]. Available from: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html [Accessed 28 June 2016]).

[105] Correa, C. (1999) Intellectual property rights and the use of compulsory licences: Options for developing countries. *South Centre* [online]. Available from: http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf [Accessed 3 June 2016], pp. 3-4.

[106] Lybecker, K. and Fowler, E. (2009) Compulsory licensing in Canada and Thailand: Comparing regimes to ensure legitimate use of the WTO rules. *Journal of Law, Medicine and Ethics,* 37(2), pp. 222-239.

[107] Abbas, M. (2013) Pros and cons of compulsory licensing: An analysis of arguments. *International Journal of Social Science and Humanity*, 3(3), p. 255.

[108] The government of Brazil used this strategy effectively to bring down the prices of AIDS drugs throughout the early 2000s. It also issued a CL in 2007 for efavirenz in its attempts to negotiate a price reduction (Abbott, F. and Reichman, J. (2007) The Doha round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of International Economic Law.* 10(4), pp. 950-952. Other LIMCs in Africa, Asia and Latin America have done the same to persuade originator pharmaceutical companies to invest in local production of a needed drug. The United States threatened to issue Bayer with a compulsory licence in 2001, when the government wanted to stockpile ciprofloxacin for defence against anthrax and the patent holder refused to provide significant price discounts. In response, Bayer drastically cut its price in response to the threat of a compulsory licence being issued (Reichman, J. (2009) Compulsory licensing of patented pharmaceutical inventions: Evaluating the options. *Journal of Law, Medicines and Ethics,* 37(2), p. 256.

[109] UNAIDS (2011) Doha +10, TRIPS flexibilities and access to antiretroviral therapy: Lessons from the past, opportunities for the future. Technical Brief. *UNAIDS* [online]. Available from: http://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA%2B10TRIPS_en_0.pdf [Accessed 8 August 2016], p.22.

[110] See WTO (2005) Amendment to the TRIPS Agreement, WT/L/641. Available from: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_wtl641_e.pdf [Accessed 8 August 2016].

[111] South Centre (2011) The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. Policy Brief 7. *South Centre* [online]. Available from: http://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf [Accessed 15 July 2016].

[112] Vandoren, P. and Eeckhaute, J. (2003) The WTO decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. *The Journal of World Intellectual Property,* 6(6), pp. 779-793; Dutfield, G.(2008) Delivering drugs to the poor: Will the TRIPS amendment help? *American Journal of Law and Medicine,* 34(2,3), pp. 107-124.

[113] As of the end of June 2016, 86 WTO Members had accepted the amendment of the TRIPS Agreement out of a total membership of 163 countries.

[114] For example, see African Union Commission and United Nations Industrial Development Organization (AUC-UNIDO) (2012) Pharmaceutical manufacturing plan for Africa. *UNIDO* [online]. Available from: http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf [Accessed 6 June 2016].

[115] Art. 8.2 TRIPS Agreement: "*Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.*"

[116] See: UNCTAD (2015) The role of competition in the pharmaceutical sector and its benefits for consumers. Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices, TD/RBP/CONF.8/3 Available from: http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf [Accessed 29 June 2016]. Contribution (181) from Duncan Matthews and Olga Gurgula. Queen Mary University, March 2016. Available from: http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/5755bda2d51cd4f6f57d96af/1465236909052/Submission+to+the+UN+HLP_on+competition++policy_final%255b1%255d.pdf [Accessed 8 August 2016].

[117] Examples include the decisions by the Competition authority of Italy to order pharmaceutical companies to grant licences to competitors for the production of an active pharmaceutical ingredient used to treat hypertrophy of the prostate in one case and the treatment of serious hospital infections in another instance. See Love, J. (2007) Recent examples of the use of compulsory licences on patents: KEI Research Note 2. *KEI* [online]. Available from: http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf [Accessed: 29 June 2016].

[118] United Nations agencies, including UNCTAD, have developed a model law on competition law, which is regularly updated: UNCTAD (2015) The model law on competition. *UNCTAD* [online]. Available from: http://unctad.org/en/Pages/DITC/CompetitionLaw/The-Model-Law-on-Competition.aspx [Accessed 7 June 2016]. And agencies like UNDP have provided expert guidance in using competition law in applying the TRIPS flexibilities: UNDP (2014) Using competition law to promote access to health technologies: A guidebook for low- and middle-income countries. *UNDP* [online]. Available from: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html [Accessed 7 June 2016]). The European Commission in its Pharmaceutical sector inquiry in 2009 (European Commission (2008) Pharmaceutical sector inquiry: Preliminary report. *European Commission* [online]. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [Accessed 7 June 2016]) and the WHO, WIPO, WTO Trilateral Study in 2012 (WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO, WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016]) also highlighted various strategies that the biopharmaceutical industry may employ that may constitute anti-competitive behaviour.

[119] To achieve policy coherence in matters of intellectual property, trade and access to health technologies, a number of countries have established national committees comprising diverse and relevant stakeholders. Zambia, for example, created an inter-ministerial committee on IP and TRIPS chaired by the vice president of the country. This was important for two reasons: first, it ensured that a common strategic vision in the best interests of the country was prioritized over the individual priorities of each member of the committee. Secondly, it elevated decision making to the top levels of national leadership, ensuring that whatever political decisions were made could immediately filter to all the line ministries that were involved in implementation (Chilambwe, J. (2016) *Intervention by representative of the Patents and Companies Registration Agency, Zambia.* High-Level Panel Hearing. Johannesburg, South Africa. 16 March 2016).

[120] As of September 2015, PEPFAR was supporting antiretroviral treatment (ART) for nearly 9.5 million people worldwide. As of mid-2015, the Global Fund has provided HIV/AIDS treatment to 8.6 million people. See InterAction (2016) HIV/AIDS, PEPFAR and The Global Fund. *InterAction* [online]. Available from: https://www.interaction.org/choose-to-invest-2017/hivaids-pepfar-global-fund [Accessed 15 July 2016].

[121] Currently, the originator company Eli Lilly is suing the government of Canada for US$ 500 million over the invalidation of Eli Lilly's patents on Strattera and Zyprexa, which are used to treat ADHD and schizophrenia, respectively. Lilly is invoking "foreign investor privileges" granted under NAFTA, to demand compensation from governments if their policies or rulings undermine "expected future profits" (*Eli Lilly and Company v The Government of Canada)*, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (Nov. 7, 2012). Available from: http://italaw.com/sites/default/files/case-documents/italaw1172.pdf [Accessed 3 June 2016]. More at: http://www.italaw.com/cases/1625 [Accessed 3 June 2016]). The US Trade Representative (USTR) furthermore, continues to put countries on its Special 301 watch list for using TRIPS flexibilities, in stark contrast to the Doha Declaration which was universally agreed to by all WTO Members (Office of the United States Trade Representative (2016) 2016 Special 301 Report. *Office of the United States Trade Representative* [online]. Available from: https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf [Accessed 3 June 2016]).

[122] Weatherall, K. (2013) TPP – Australian section-by-section analysis of the enforcement provisions of the August leaked draft. *Sydney Law School Research Paper No. 13/84* [online]. Available from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2357259 [Accessed 21 July 2016]. See also Article 18.78, Chapter 18 (Intellectual Property), Full Text of the TPP. Available from: https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf [Accessed 18 July 2016].

[123] Contribution (72) from Sanya Reid Smith, Third World Network, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/28/third-world-network [Accessed 20 June 2016]. See also: Mercurio, B. (2006) TRIPS-Plus provisions in FTAs: Recent trends. In: Bartels, L. and Ortino, F. (eds.) *Regional trade agreements and the WTO legal system*. Oxford Scholarship [online]. Available from: https://www.researchgate.net/publication/228154939_TRIPS-Plus_Provisions_in_FTAs_Recent_Trends [Accessed 20 June 2016]. See also: Lindstrom, B. (2010) Scaling back TRIPS-Plus: An analysis of intellectual property provisions in trade agreements and implications for Asia and the Pacific. *Journal of International Law and Politics,* 42(3), pp. 917-980. See also: Lopert, R. and Gleeson, D. (2013) The high price of "free" trade: United States trade agreements and access to medicines. *The Journal of Law, Medicine and Ethics*, 41(1), pp. 119-223. See also: WHO, WIPO and WTO (2012) Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade. *WHO, WIPO and WTO* [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf [Accessed 20 June 2016]. See also: Office of the United States Trade Representative (2016) TPP full text. *USTR* [online]. Available from: https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [Accessed 18 July 2016].

[124] This is more than seven times of what the next-largest funder, the European Commission, spent. See Viergever, R. and Hendriks, T. (2015) The 10 largest public and philanthropic funders of health research in the world: What they fund and how they distribute their funds. *Health Research Policy and Systems*, 14(12).

[125] 35 United States Code 200 "*It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and non-profit organizations, including universities; to ensure that inventions made by non-profit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions; and to minimize the costs of administering policies in this area*."

[126] Prior to 1980, less than 5% of the 28,000 patents being held by federal agencies had been licensed out. See: United States General Accounting Office (1998) Report to Congressional Committees, technology transfer: Administration of the Bayh-Dole Act by research universities, GAO/RCED-98-126. *United States General Accounting Office* [online]. Available from: http://www.gao.gov/archive/1998/rc98126.pdf [Accessed 21 July 2016].

[127] Grimaldi, R., *et al*. (2011) 30 years after Bayh–Dole: Reassessing academic entrepreneurship. *Research Policy*, 40, pp. 1045-1057.

[128] Legislation similar to Bayh-Dole has been introduced in Brazil (*Innovation and Research in Science and Technology 2004* or Law No. 10.973 of 2004), China (*Law of the People's Republic of China on Scientific and Technological Progress 2*007), Denmark (*Act on Inventions at Public Research Institutions 1999*), Germany (*Arbeitnehmererfindungsgesetz* 2002, i.e. the abolition of *Hochschullehrerprivileg* or 'Professor's Privilege'), Malaysia (*The Government Circular on the Management of Intellectual*

Property Owned by the Government and the Distribution of Royalties 1999 and the *Intellectual Property Commercialisation Policy for Research and Development Projects Funded by the Government of Malaysia 2009*), Singapore (*Patents Act 1994*) and South Africa (*Intellectual Property Rights from Publicly Financed Research and Development Act 2008*).

[129] Loise, V. and Stevens, A. (2010) The Bayh-Dole Act turns 30. *Science Translational Medicine*, 2(5), p. 2.

[130] So. A., *et al*. (2008) Is Bayh-Dole good for developing countries? Lessons from the US experience. *PLoS Biology*, 6(10), e262.

[131] Boettiger, S. and Bennett, A. (2006) Bayh-Dole: If we knew then what we know now. *Nature Biotechnology*, 24, pp. 320-323.

[132] For instance, in 2001 Yale University granted Bristol-Myers Squibb an exclusive license to the antiretroviral stavudine, which BMS priced at US$ 1,600 per patient per year—out of reach for poor countries with high HIV prevalence. Under pressure from civil society, Yale and BMS extended the license to a South African generic manufacturer, which dropped the price to US$ 55 (Chen, C., *et al*. (2010) The silent epidemic of exclusive university licensing policies on compounds for neglected diseases and beyond. *PLoS Neglected Tropical Diseases,* 4(3), e570).

[133] Lee, W.H. (2015) Open access target validation is a more efficient way to accelerate drug discovery. *PLoS Biology*, 13(6), e1002164.

[134] Kesselheim, A. (2010) Using market-exclusivity incentives to promote pharmaceutical innovation. *New England Journal of Medicine,* 363, pp.1855-1862.

[135] Chokshi, D. (2006) Improving access to medicines in poor countries: The role of universities. *PLoS Med*icines, 3(6), pp. 723-726. See also: Kapczynski, A. (2005) Addressing global health inequalities: An open licensing approach for university innovations. *Berkeley Technology Law Journal*, 20(2), pp. 1031-1114.

[136] Trouiller, P., *et al*. (2002) Drug development for neglected diseases: A deficient market and a public-health policy failure. *The Lancet,* 359, pp. 2188-2189.

[137] The Review on Antimicrobial Resistance. (2016) Tackling drug-resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government* [online]. Available from: http://amr-review.org/ [Accessed: 27 June 2016]. See also: Clift, C., *et al.* (2015) Towards a new global business model for antibiotics: Delinking revenues from sales. Report from the Chatham House Working Group on New Antibiotic Business Models. *Chatham House* [online]. Available from: https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20151009NewBusinessModelAntibioticsCliftGopinathanMorelOuttersonRottingenSo.pdf [Accessed 29 June 2016], p. vii.

[138] About 47% of the novel drugs approved in 2015 (21 of 45) were approved to treat rare or 'orphan' diseases that affect 200,000 or fewer Americans. See: US Drug and Food Administration (2016) Novel drugs summary 2015. *US Drug and Food Administration* [online]. Available from: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm [Accessed 27 June 2016].

[139] Frenk, J. and Moon, S. (2013) Governance challenges in global health. *The New England Journal of Medicine,* 368, p. 939.

[140] For a comprehensive survey of existing initiatives, see Kiddell-Monroe, R., Greenberg, A. and Basey, M. (2016) Re:Route: A map of the alternative biomedical R&D landscape. *Universities Allied for Essential Medicines (UAEM)* [online]. Available from: http://www.altreroute.com/assets/download/UAEM_Reroute_Report.pdf [Accessed 2 June 2016].

[141] The Commission's recommendations for fostering innovation and access are still relevant today. However, the focus of the Commission on low- and middle-income countries was narrower than this Panel's mandate. Commission on Intellectual Property Rights, Innovation and Public Health (2006) Public health, innovation and intellectual property rights. *WHO* [online]. Available from: http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1 [Accessed 2 June 2016].

[142] Some criticism has arisen in response to the current model of AMC as it has acted as a purchasing mechanism instead of pulling new invention from late stage development to the market at affordable price. See Médecins Sans Frontières (MSF) (n.d.) Advance market commitment. *MSF* [online]. Available from: http://www.msfaccess.org/spotlight-on/advance-market-commitment [Accessed 8 August 2016].

[143] The WIPO Re:Search consortium, for example, connects the assets and resources of pharmaceutical companies, such as compound libraries, to academic or non-profit researchers with novel ideas for product development (See: Ramamoorthi, R., Graef, K. and Dent, J. (2014) WIPO Re:Search: Accelerating anthelmintic development through cross-sector partnerships. *International Journal for Parasitology: Drugs and drug resistance*, 4(3), pp. 220-225). And a particularly prolific PDP is DNDi, established in 2003 to catalyse scientific projects to meet the needs of neglected patients. One of DNDi' s most significant releases, NECT, the first new, improved treatment for advanced state sleeping sickness in 25 years, was the result of a six-year partnership of NGOs, the WHO, governments and originator pharmaceutical companies (See: DNDi (2014) An innovative approach to R&D for neglected patients: Ten years of experience and lessons learned by DNDi. *DNDi* [online]. Available from: http://www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf [Accessed 31 May 2016]).

[144] Data from 2014. Policy Cures (2015) Neglected disease research and development: The Ebola effect. *G-FINDER Report 2015* [online]. Available from: http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf [Accessed 2 June 2016], p. 76.

[145] Uniting to Combat NTDs (2016) The London Declaration. *Uniting to Combat NTDs* [online]. Available from: http://unitingtocombatntds.org/london-declaration [Accessed 27 June 2016].

[146] Policy Cures (2015) Neglected disease research and development: The Ebola effect. *G-FINDER Report 2015* [online]. Available from: http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf [Accessed 2 June 2016], p. 5.

[147] Policy Cures (2015) Neglected disease research and development: The Ebola effect. *G-FINDER Report 2015* [online]. Available from: http://policycures.org/downloads/Y8%20

GFINDER%20full%20report%20web.pdf [Accessed 2 June 2016], p. 69.

[148] For example, in 2016 the Japanese government replenished the Global Health Innovative Technology Fund/UNDP program with an extra US$ 130 million, adding to an earlier investment of US$ 70 million made in 2013 (see: Global Health Innovative Technology Fund, "Government of Japan announces decision to contribute US$ 130 million to GHIT Fund/UNDP replenishment," *GHIT Fund* – Press Release [online]. Available from: https://www.ghitfund.org//about/mediacenter/pressdetail/detail/164 [Accessed 2 June 2016]). Another important development is the announcement by the UK government in late 2015 that it would be establishing the £1 billion Ross fund which includes £350 million earmarked for the development of new health technologies to treat Malaria, TB, NTDs and emergent infections (see: UK Department of Health and UK Aid (2016) Ross Fund – Summary. *Department for International Development* [online]. Available from: https://www.gov.uk/government/news/the-ross-fund-combatting-the-worlds-most-serious-diseases [Accessed 3 June 2016]). The Global Health Investment Fund (GHIF) furthermore, combines investments from donor governments and the Gates Foundation with private sector expertise to form a US$ 108 million PDP investing in neglected diseases including HIV, Malaria and NTDs (see: GHIF (n.d.) An innovative response to the challenge of financing global health research and development. *GHIF* [online]. Available from: http://www.ghif.com/ [Accessed 3 June 2016]).

[149] Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance (2016). Available from: http://amr-review.org/sites/default/files/Declaration_of_Support_for_Combating_AMR_Jan_2016.pdf [Accessed 27 June. 2016].

[150] MSF, for instance, points out that even at the lowest, subsidized prices, the cost of fully vaccinating a child increased 68-fold from 2001 to 2014, "calling into question the sustainability of immunisation programmes after countries lose donor support." (See MSF (2015) The right shot: Bringing down barriers to affordable and adapted vaccines (2nd ed.). *MSF* [online]. Available from: http://cdn.doctorswithoutborders.org/sites/usa/files/attachments/the_right_shot_2nd_edition.pdf [Accessed 31 May 2016].

[151] WHO Secretariat (2016) Global action plan on antimicrobial resistance (A69/24 Add.1). *WHO 69th World Health Assembly* [online]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_24Add1-en.pdf [Accessed 2 June].

[152] WHO (2016) Investing in the development of new antibiotics and their conservation. *WHO* [online]. Available from: http://www.who.int/phi/implementation/consultation_imnadp/en/ [Accessed 2 June].

[153] EU Innovative Medicines Initiative (IMI) (2010) Drive-AB – Driving re-investment in R&D and responsible antibiotic use. *IMI* [online]. Available from: http://www.imi.europa.eu/content/drive-ab [Accessed 2 June].

[154] See, e.g.: The Review on Antimicrobial Resistance (2016) Tackling drug resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government* [online]. Available from: http://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf [Accessed 2 June 2016]. See also: Clift, C., *et al.* (2015) Towards a new global business model for antibiotics: Delinking revenues from sales. Report from the Chatham House Working Group on New Antibiotic Business Models. *Chatham House* [online]. Available from: https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20151009NewBusinessModelAntibioticsCliftGopinathanMorelOuttersonRottingenSo.pdf [Accessed 29 June 2016], p. 17.

[155] World Health Assembly (WHA61.21) resolution (2008) Global strategy and plan of action on public health, innovation and intellectual property. *WHO* [online]. Available from: http://apps.who.int/medicinedocs/documents/s21429en/s21429en.pdf [Accessed 15 August 2016].

[156] An open-ended meeting with Member States was recently convened at the WHO in Geneva. (See WHO (2016) Follow up to the report of the Consultative Expert Working Group on Research and Development: Financing and coordination – Report of the open-ended meeting of Member States (A69/40). Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_40-en.pdf [Accessed 31 May 2016]).

[157] United Nations General Assembly (2015) Transforming our world: The 2030 Agenda for Sustainable Development, A/70/L.1. Available from: http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E [Accessed 18 July 2016], para. 48.

[158] Contribution (17) from N. Hassoun, Binghamton University, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/16/contributionn-hassoun [Accessed 8 August 2016]. See also, e.g., Contribution (4) from Laura Laughlin, Sanofi Pasteur, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionlaura-laughlin [Accessed 8 August 2016].

[159] WHO (n.d.) About the Global Observatory on Health R&D. *WHO* [online]. Available from: http://www.who.int/research-observatory/about/en/ [Accessed 2 June 2016].

[160] WHO (2016) Submission to the High-Level Panel on Access to Medicines. Available from: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56e746279f7266a586c2b893/1457997352055/WHO_HLP_Submission_7Mar2016.pdf [Accessed 2 June 2016], pp. 15-16.

[161] High-Level Panel on the Global Response to Health Crises (2016) Protecting humanity from future health crises. Report of the High-Level Panel on the Global Response to Health Crises (Advance unedited copy) [online]. Available from: http://www.un.org/News/dh/infocus/HLP/2016-02-05_Final_Report_Global_Response_to_Health_Crises.pdf [Accessed 6 June 2016], p. 4. We acknowledge the important contributions of that panel, some of which overlaps the broader mandate of this one.

[162] The United States spends US$ 1 billion on such health programmes, compared with US$ 100 billion on counterterrorism. See: Yamada, T., Ogawa, V.A., and Freire, M. (2016) Policy: Security spending must cover disease outbreaks. *Nature*, 533:7601, pp. 29-31. See also: Sands, P., *et al.* (2016) The neglected dimension of global security - A framework for countering infectious-disease crises. *The New England Journal of Medicine,* 374(13), pp. 1281-1287.

[163] Pike, J., *et al.* (2014) Economic optimization of a global strategy to address the pandemic threat. *Proceedings of the National Academy of Sciences*, 111(52), pp. 18519-18523.

[164] Centers for Disease Control and Prevention (CDC) (2016) 2014 Ebola outbreak in West Africa - case counts. *CDC* [online]. Available from: http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html [Accessed 15 August 2016].

[165] Fauci, A. S., and Morens, D. M. (2016) Zika virus in the Americas—Yet another arbovirus threat. *New England Journal of Medicine,* 374(7), pp. 601-604.

[166] The efficacy of the rVSV-ZEBOV vaccine in nonhuman primates was demonstrated over 10 years ago (see Jones, S., *et al.* (2005) Live attenuated recombinant vaccine protects nonhuman primates against Ebola and Marburg viruses. *Nature Medicine*, 11(7), pp. 786-790). See also: Grady, D. (2014) Ebola vaccine, ready for test, sat on the shelf. *The New York Times* [online]. October 23, 2014. Available from: http://www.nytimes.com/2014/10/24/health/without-lucrative-market-potential-ebola-vaccine-was-shelved-for-years.html?_r=1 [Accessed 29 June 2016].

[167] Moon, S. *et al*. (2015) Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola. *The Lancet,* 386.10009, pp. 2204-2221.

[168] Centers for Disease Control and Prevention (CDC) (2016) 2014 Ebola outbreak in West Africa - case counts. *CDC* [online]. Available from: http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html [Accessed 29 June 2016].

[169] Consultative Expert Working Group on Research and Development (2012) Research and development to meet health needs in developing countries: Strengthening global financing and coordination. *WHO* [online]. Available from: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf [Accessed 2 June 2016], p. 10.

[170] See, e.g. Bloemen, S. and Hammerstein, D. (2012) Time for the EU to lead on innovation – EU policy opportunities in biomedical innovation and the promotion of public knowledge goods. *Health Action International* (*HAI) Europe and TACD* [online]. Available from: http://haieurope.org/wp-content/uploads/2012/04/HAI-Europe_TACD-EU-Innovation-Paper.pdf [Accessed 2 June 2016] as well as WIPO Committee on Development and Intellectual Property (CDIP) (2014) Alternatives to the patent system that are used to support R&D efforts, including both push and pull mechanisms, with a special focus on innovation-inducement prizes and open source development models, CDIP/14/INF/12. Available from: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_14/cdip_14_inf_12.pdf [Accessed 7 June 2016].

[171] The Review on Antimicrobial Resistance (2016) Tackling drug-resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government*. [online]. Available from: http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf [Accessed 28 June 2016], p. 67.

[172] The Review on Antimicrobial Resistance (2016) Tackling drug-resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government* [online]. Available from: http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf [Accessed 28 June 2016], p. 7.

[173] WHO and TDR (2016) Health Product Research and Development Fund: A proposal for financing and operation. *WHO on behalf of TDR* [online]. Available from: http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295_eng.pdf?ua=1 [Accessed 27 June 2016].

[174] World Health Assembly (2013) Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination 66th World Health Assembly (WHA66.22) [online]. Available from: http://apps.who.int/iris/bitstream/10665/150173/1/A66_R22-en.pdf?ua=1&ua=1 [Accessed 27 June 2016].

[175] Consultative Expert Working Group on Research and Development (2012) Research and development to meet health needs in developing countries: Strengthening global financing and coordination. *WHO* [online]. Available from: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf [Accessed 2 June 2016], pp. 114-120. See also: Moon, S., *et al.* (2012) Innovation and access to medicines for neglected populations: Could a treaty address a broken pharmaceutical R&D system? *PloS Medicine,* 9(5), e1001218.

[176] Leading Group on Innovative Financing for Development (2010) The Leading Group: Laboratory of expertise and diplomatic tool for development finance. *The Leading Group* [online]. Available from: http://www.leadinggroup.org/rubrique69.html [Accessed 8 August 2016].

[177] United Nations (2015) Addis Ababa Action Agenda of the third international conference on financing for development. *United Nations* [online]. Available from: http://www.un.org/esa/ffd/wp-content/uploads/2015/08/AAAA_Outcome.pdf [Accessed 8 August 2016], para.69.

[178] For the purposes of this report, good governance is made up of transparency (access to information relevant to the purpose of that governance); participation of those with a stake in the governance decisions; and accountability, including access to recourse when commitments are not honoured. See Frenk, J. and Moon, S. (2013) Governance challenges in global health. *The New England Journal of Medicine,* 368(10), pp. 939-940.

[179] SDG Targets: SDG target 16.6: Develop effective, accountable and transparent institutions at all levels; 17.13: Enhance global macroeconomic stability, including through policy coordination and policy coherence; 17.14: Enhance policy coherence for sustainable development; 17.15: Respect each country's policy space and leadership to establish and implement policies for poverty eradication and sustainable development; 17.16: Enhance the global partnership for sustainable development, complemented by multi-stakeholder partnerships that mobilize and share knowledge, expertise, technology and financial resources, to support the achievement of the sustainable development goals in all countries, in particular developing countries; 17.17: Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships. See United Nations General Assembly (2015) Transforming our world: The 2030 Agenda for Sustainable Development, A/70/L.1. Available from: https://sustainabledevelopment.un.org/post2015/transformingourworld [Accessed 27 June 2016].

[180] Existing human rights accountability mechanisms can be found at national and international levels. Whereas the former

include judicial or administrative enforcement mechanisms (e.g. litigation before tribunals, national human rights commissions or parliamentary processes), the latter have more an oversight function (e.g. United Nations Commission on Human rights, Inter-American Commission on Human Rights, African Commission on Human and Peoples' Rights European Court of Human Rights, Universal Periodic Review). See also: OHCHR (2013) Who will be accountable? Human rights and the post-2015 development agenda. *OHCHR and Center for Economic and Social Rights* [online]. Available from: http://www.ohchr.org/Documents/Publications/WhoWillBeAccountable.pdf [Accessed 27 June 2016].

[181] Doha WTO Ministerial (2001) Ministerial declaration, WT/MIN(01)/DEC/1, para. 49. Available from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#organization [Accessed 8 August 2016].

[182] UN agencies and multilaterals working on issues of health technology innovation and access include: WHO, WIPO, WTO, UNIDO, UNCTAD, UNICEF, UNHCHR, UNAIDS and UNDP.

[183] See e.g. Weiss, T. and Wilkinson, R. (eds.) (2014) International organizations and global governance. London: Routledge. Recognition of insufficient cooperation led to, e.g., the creation of the trilateral cooperation between WHO, WIPO and WTO. See: Krattiger A., *et al*. (2015) Promoting medical innovation and access, together. Trilateral Cooperation between WHO, WIPO and WTO. Global challenges brief on trilateral cooperation. *WIPO* [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_10.pdf [Accessed 2 June 2016].

[184] See, e.g., Gulrajani, N., Mulley, S. and Woods, N. (2005) Who needs more coordination? The United Nations and development assistance. *Journal of International Law and International Relations*, 2(1), pp. 27-39.

[185] WHO (2015) Terms of reference for the United Nations Interagency Task Force on the Prevention and Control of Noncommunicable Diseases. *WHO* [online]. Available from: http://www.who.int/nmh/ncd-task-force/un-tf.PDF?ua=1 [Accessed 2 June 2016].

[186] United Nations General Assembly Resolution adopted by the General Assembly on 25 September 2015 (2015) A/RES/70/1. Available from: https://sustainabledevelopment.un.org/post2015/transformingourworld [Accessed 18 July 2016].

[187] See: MDG Gap Task Force (2008) Millennium Development Goal 8 – Delivering on the global partnership for achieving the millennium development goals. *United Nations* [online]. Available from: http://www.un.org/millenniumgoals/pdf/MDG%20Gap%20Task%20Force%20Report%202008.pdf [Accessed 27 June 2016] and MDG Gap Task Force (2015) Millennium Development Goal 8 – Taking stock of the global partnership for development. *United Nations* [online]. Available from: http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2015/2015GAP_FULLREPORT_EN.pdf [Accessed 27 June 2016].

[188] Secretary-General of the United Nation's Commission on Information and Accountability for Women's and Children's Health (CoIA) (2011) *Keeping promises, measuring results. Every Woman Every Child* [online]. Available from: http://www.who.int/topics/millennium_development_goals/accountability_commission/Commission_Report_advance_copy.pdf?ua=1 *[Accessed 2 June 2016],* p. 19. In 2015 the iERG was succeeded by a nine-member Independent Accountability Panel, which monitors progress on the SDGs for women's and children's health. *Every Woman Every Child* (n.d.) *Announcement of Every Woman Every Child's Independent Accountability Panel* [online]. Available from*:* http://everywomaneverychild.org/accountability/independent-accountability-panel [Accessed 2 June 2016].

[189] See, e.g., OECD (2007) High-Level Forum on Medicines for Neglected and Emerging Infectious Disease: Noordwijk Medicines Agenda. *OECD* [online]. Available from: https://www.oecd.org/pcd/38845838.pdf [Accessed 7 June 2016]. A national health multi-stakeholder working group and a ministerial working group were credited for improving policy coherence in Zambia, and this process is being emulated in Lesotho (see Contribution (9) from Nthabiseng Meriam Mabokang Sekokotoana, Lesotho Ministry of Law, March 2016. Accessed from: http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionnthabiseng-meriam-mabokang-sekokotoana [Accessed 7 June 2016]).

[190] Tussie, D and Saguier, M. (2011) The sweep of asymmetric trade negotiations: Overview. In: Bilal, S., *et al.* (ed.) The sweep of asymmetric trade negotiations: Problems, processes and prospects. *Latin American Trade Network* [online]. Available from: http://www19.iadb.org/intal/intalcdi/PE/2011/08165.pdf [Accessed 30 June 2016], pp. 1-16.

[191] Shadow reports are submitted to the United Nations independently of government on issues such as the rights of the child or the HIV/AIDS response; they may be presented to all of the human rights treaty monitoring bodies. They may address the specific treaty articles or specifically mirror the country's common core document (CCD). Shadow reports may also be provided to the Human Rights Council for the Universal Periodic Review (UPR). See: International Women's Rights Action Watch (IWRAW) (n.d.) Shadow reporting to United Nations treaty bodies. *IWRAW* [online]. Available from: http://www1.umn.edu/humanrts/iwraw/reports.html [Accessed 27 June 2016].

[192] CIVICUS (2016) State of civil society report. *CIVICUS* [online]. Available from: http://www.civicus.org/images/documents/SOCS2016/summaries/SoCS-full-review.pdf [Accessed 18 July 2016].

[193] In the same resolution, the United Nations Human Rights Council established the United Nations Working Group on Business and Human Rights. See: United Nations General Assembly (2011) Resolution 17/4 adopted by the Human Rights Council: Human rights and transnational corporations and other business enterprises, A/HRC/RES/17/4. Available from: https://documents-dds-ny.un.org/doc/RESOLUTION/GEN/G11/144/71/PDF/G1114471.pdf?OpenElement [Accessed 18 July 2016]. See also: OHCHR (2011) Guiding principles on business and human rights: Implementing the United Nations 'Protect, Respect and Remedy Framework'. *OHCHR and United Nations* [online]. Available from: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf [Accessed 2 June 2016].

[194] See e.g. Forman, L. and MacNaughton, G. (2015) Moving theory into practice: Human rights impact assessment of

intellectual property rights in trade agreements. *Journal of Human Rights Practice*, 7(1), pp. 109-138.

[195] Office of the High Commissioner for Human Rights (OHCHR) (2011) Guiding principles on business and human rights: Implementing the United Nations 'Protect, Respect and Remedy Framework'. *OHCHR and United Nations* [online]. Available from: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf [Accessed 2 June 2016].

[196] Moon, S. (2013) Respecting the right to access to medicines: Implications of the United Nations Guiding Principles on Business and Human Rights for Pharmaceutical Companies. *Health and Human Rights Journal*, 15(1), pp. 32-43. For further discussion of the human rights responsibilities of pharmaceutical companies, see: Marks, S. (2009) Access to essential medicines as a component of the right to health, in: Clapham, A. and Robinson, M. (eds.) *Realizing the right to health.* Zurich, Switzerland: Rüfer and Rub, pp. 82-101.

[197] General Comment 14 on the ICESCR affirms that "*while only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society*"—including private businesses—"*have responsibilities regarding the realization of the right to health.*" See Committee on Economic, Social and Cultural Rights (2000) The right to the highest attainable standard of health, General Comment No. 14, E/C.12/2000/4, para. 42. Available from: http://apps.who.int/disasters/repo/13849_files/o/UN_human_rights.htm [Accessed 8 June 2016]. The Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, furthermore, reported to the General Assembly in 2008, elaborated on those responsibilities, discussing such issues as patents, clinical trials and prices (United Nations General Assembly (2008) Report of the Special Rapporteur on the Right of Everyone to the enjoyment of the highest attainable standard of physical and mental health, A/63/263. Available from: http://www.who.int/medicines/areas/human_rights/A63_263.pdf [Accessed 8 June 2016]). The United Nations Global Compact, currently signed by 8,902 companies in 166 countries, encourages corporate social responsibility regarding human rights, labour, the environment and anti-corruption efforts (see United Nations Global Compact (n.d.) Available from: https://www.unglobalcompact.org/ [Accessed 2 June 2016]). Furthermore, the United Nations Sub-Commission on the Promotion and Protection of Human Rights recognized that although states bear the primary responsibility to promote, respect and protect human rights, "*transnational corporations and other business enterprises…are also responsible for promoting and securing…human rights*". See: Sub-Commission on the Promotion and Protection of Human Rights (2003) Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights, E/CN.4/Sub.2/2003/12/Rev.2. Available from: https://documents-dds-ny.un.org/doc/UNDOC/GEN/G03/160/08/PDF/G0316008.pdf?OpenElement [Accessed 13 July 2016]. See also: OECD (2011) OECD Guidelines for Multinational Enterprises. *OECD* [online]. Available from: http://www.oecd.org/daf/inv/mne/48004323.pdf [Accessed 13 July 2016].

[198] See UN Doc. No. E/C.12/FRA/CO/4. Unofficial translation available in The Global Initiative for Economic, Social and Cultural Rights (2016) Human rights law sources: United Nations pronouncements on extra-territorial obligations. *Global Initiative for Economic, Social and Cultural Rights* Working Paper [online]. Available from: http://globalinitiative-escr.org/wp-content/uploads/2016/06/160627-Human-Rights-Law-Sources-ETOs.pdf [Accessed 19 July 2016].

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[200] OHCHR (2011) Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy Framework'. *OHCHR and United Nations* [online]. Available from: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf [Accessed 2 June 2016], para.17.

[201] Shift (2014) Evidence of corporate disclosure relevant to the United Nations Guiding Principles on Business and Human Rights. *Shift* [online]. Available from: http://www.shiftproject.org/resources/publications/evidence-corporate-disclosure-relevant-guiding-principles/ [Accessed 27 June 2016]. See also: F. Hoffmann-La Roche Ltd (n.d.) Human rights. *F. Hoffmann-La Roche Ltd* [online]. Available from: http://www.roche.com/sustainability/what_we_do/for_employees/human_rights.htm [Accessed 27 June 2016].

[202] See: United Nations Global Compact (n.d.) Let's make global goals local business. *United Nations Global Compact* [online]. Available from: https://www.unglobalcompact.org/ [Accessed 2 August 2016]. It has been suggested that access to medicines could be added as another area of focus.

[203] The NIH and some foundations and donors publish their grants' recipients and amounts. For example, see the NIH Research Portfolio Online Reporting Tools (RePORT). National Institutes of Health (n.d.) NIH RePORT. *U.S. Department of Health and Human Services* [online]. Available from: https://projectreporter.nih.gov/reporter.cfm [Accessed 19 July 2016].

[204] The costs of failed research are also included in these estimates. See DiMasi, J., Grabowski, H. and Hansen, R. (2016) Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, pp. 20-33.

[205] See e.g. Avorn, J. (2015) The US$ 2.6 billion pill – methodologic and policy considerations. *The New England Journal of Medicine*, 372, pp. 1877-1879.

[206] DNDi (2014) An innovative approach to R&D for neglected patients: Ten years of experience and lessons learned by DNDi. *DNDi* [online]. Available from: http://www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf [Accessed 31 May 2016]. A 2011 article in the London School of Economics and Political Science journal *BioSocieties* reported the median real cost of R&D for a new medicine to be US$ 43.4 million, compared to the mean of US$ 58 million, arguing that the median cost would be the more accurate to use, but explaining that it is the higher mean cost that industry most often refers to. Light, D. and Warburton, R. (2011) Demythologizing the high costs of pharmaceutical research. *BioSocieties*, 6(1), pp. 13-14.

[207] Gagnon, M.-A. and Lexchin, J. (2008) The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States, *PLoS Medicine*, 5(1), e1.

[208] See: WHO (2013) Transaction prices for antiretroviral medicines from 2010 to 2013: WHO AIDS medicines and diagnostics services: Global price reporting mechanism - Summary report. *WHO* [online]. Available from: http://www.who.int/hiv/pub/amds/amds_globalpricereport/en/ [Accessed 31 May 2016]. The Global Fund's Price and Quality Reporting Tool also maintains a public database of prices paid for HIV, tuberculosis and malaria medicines (see the Global Fund (n.d.) Price and quality reporting. *The Global Fund* [online]. Available from: http://www.theglobalfund.org/en/pqr/ [Accessed 31 May 2016]). The WHO HAI Project on Medicine Prices and Availability has surveyed a range of data on essential medicines along the supply chain from manufacturer to pharmacy in 50 LIMCs (see Cameron A., *et al.* (2008) Medicine prices, availability and affordability in 36 developing and middle-income countries: A secondary analysis. *Lancet*, 373(9659), pp. 240-249. Individual countries have also implemented policies to improve transparency, such as the Netherlands Expensive Medications Monitor (see Contribution (60) from the Ministry of Foreign Affairs of the Kingdom of the Netherlands, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/27/ministry-of-foreign-affairs-the-kingdom-of-the-netherlands [Accessed 6 June 2016]) and transparency and fair-bidding reforms in South Africa's tender process for ARVs, which helped reduce the cost of these medicines by more than half - and double the number of people treated. See UNAIDS (2013) Efficient and sustainable HIV responses: Case studies on country progress. *UNAIDS Case Study* [online]. Available from: http://www.unaids.org/sites/default/files/media_asset/JC2450_case-studies-country-progress_en_0.pdf [Accessed 31 May 2016], pp. 11-12.

[209] WHO (2015) (V3P Web Platform. *WHO* [online]. Available from: http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/en/ [Accessed 30 June 2016].

[210] HAI and WHO (n.d.) Database of medicines prices, availability, affordability and price components. *HAI* [online]. Available from: http://www.haiweb.org/MedPriceDatabase/ [Accessed 27 June 2016]. MSF (2016) Untangling the web of antiretroviral price reductions. 18th ed. *MSF Access* [online]. Available from: http://www.msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf [Accessed 2 August 2016].

[211] Discounts and mark-ups and discounts vary between countries, see for example Henry, D. and Searles, A. (2012) Pharmaceutical pricing policy. Chapter 9, in: Management Sciences for Health. *MDS-3: Managing access to medicines and health technologies* (3rd ed.) [online]. Available from: http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf [Accessed 7 June 2016].

[212] Robertson, J., Walkom, E. and Henry, D. (2009) Transparency in pricing arrangements for medicines listed on the Australian Pharmaceutical Benefits Scheme. *Australian Health Review*, 33(2), pp. 192-199.

[213] House of Commons Committee of Public Accounts UK (2013) Access to clinical trial information and the stockpiling of Tamiflu - Thirty-fifth Report of Session 2013–14. *London: The Stationery Office Limited*. Available from: http://www.publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/295/295.pdf [Accessed 7 June 2016], p. 3.

[214] PhRMA (2015) 2015 profile: Biopharmaceutical research industry 2015. *PhRMA* [online]. Available from: http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf [Accessed 31 May 2016], p. 26.

[215] Mann, J., *et al.* (2006) ACNP Task force report on SSRIs and suicidal behavior in youth. *Neuropsychopharmacology*, 31(3), pp. 473-492.

[216] The International Ethical Guidelines issued by the International Organization of Medical Sciences (IOM) and the WHO, as well as the Helsinki Declaration, adopted by the World Medical Association in 1964 and subsequently amended, list among these ethical duties the complete, accurate and timely publication of research results, including negative and inconclusive ones (Council for International Organizations of Medical Sciences (CIOMS) and WHO (2002) International ethical guidelines for biomedical research involving human subjects. *CIOMS* [online]. Available from: http://www.cioms.ch/publications/layout_guide2002.pdf [Accessed 31 May 2016]; World Medical Association (WMA) (1964, lastly amended in 2013) Declaration of Helsinki - Ethical principles for medical research involving human subjects [online]. Available from: http://www.wma.net/en/30publications/10policies/b3/ [Accessed 19 July 2016]). The Nuffield Council on Bioethics, a trio of public and private UK medical research funders, published ethical guidelines on research related to developing countries (see Nuffield Council on Bioethics (2014) The ethics of research related to healthcare in developing countries. *Nuffield Council on Bioethics* [online]. Available from: http://nuffieldbioethics.org/wp-content/uploads/2014/07/Ethics-of-research-related-to-healthcare-in-developing-countries-I.pdf [Accessed 1 June 2016]). The WHO Handbook for Good Clinical Research Practice contains guidelines for recording, handling and storing of clinical trial data so that it may be properly reported, interpreted and verified (see WHO (2002) Handbook for good clinical research practice. *WHO* [online]. Available from: http://apps.who.int/prequal/info_general/documents/GCP/gcp1.pdf [Accessed 31 May 2016]).

[217] For instance, a United States Senate Finance Committee investigation of deaths in patients taking the medicine Avandia concluded that regulators were "too cozy with drug-makers" and had not interfered when they knew the risks of the medicine (United States Senate Committee on Finance (2010) Grassley, Baucus Release Committee report on avandia. *United States Senate Committee on Finance* [online]. Available from: http://www.finance.senate.gov/release/grassley-baucus-release-committee-report-on-avandia [Accessed 31 May 2016]). An independent audit found that only 1 in 5 registered trials were published within the FDA's mandated one year, but none was fined for failure to report. Ross, J., *et al.* (2012) Publication of NIH funded trials registered in ClinicalTrials.gov: Cross sectional analysis. *British Medical Journal,* 344:d7292.

[218] Lewis, T., Reichman, J. and So, A. (2007) The case for public funding and public oversight of clinical trials. *The Economists' Voice*, 4(1), pp. 1-4. See also: Doshi, P., Jefferson, T. and Del Mar, C. (2012) The imperative to share clinical study reports: Recommendations from the tamiflu experience. *PLoS Med,* 9(4), e1001201.

[219] See, e.g., Dickersin, K. (1990) The existence of publication bias and risk factors for its occurrence. *The Journal of the American Medical Association,* 263(10), pp. 1385-1389; Chalmers, T., Frank, C. and Reitman, D. (1990) Minimizing the three stages of publication bias. *The Journal of the American Medical Association,* 263(10), pp. 1392-1395. COMPARE – Tracking Switched Outcomes in Clinical Trials (n.d.) *Centre for Evidence-Based Medicine, University of Oxford* [online]. Available from: http://compare-trials.org/results [Accessed 31 May 2016]. Researchers at Oxford University examined trials published in the five most prestigious English language medical journals and found evidence of this practice in most of the studies they reviewed.

[220] WHO (n.d.) International Clinical Trials Registry Platform (ICTRP). *WHO* [online]. Available from: http://www.who.int/ictrp/en/ [Accessed 31 May 2016].

[221] For further information, see: European Medicines Association (EMA) (2016) Background to clinical data publication policy. *EMA* [online]. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp [Accessed 19 July 2016].

[222] WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO and WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016], pp. 135-136. See also UNDP (2012) Patent information and transparency: A methodology for patent searches on essential medicines in developing countries. *UNDP* [online]. Available from: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/a-methodology-for-patent-searches-on-essential-medicines-in-deve.html [Accessed 31 May 2016], pp 5, 9-11.

[223] See, e.g., European Commission (EC) Competition DG (2009) Pharmaceutical sector inquiry: Final report. *EC Competition DG* [online]. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf [Accessed 3 June 2016], p. 201.

[224] Heller, M. and Eisenberg, R. (1998) Can patents deter innovation? The anticommons in biomedical research. *Science,* 280(689), pp. 699-700.

[225] For a discussion of patent thickets, see WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO and WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016], pp. 135-136. Furthermore, a Markush claim can allow one patent filing to cover millions of molecules. See: Correa, C. (2011) Pharmaceutical innovation, incremental patenting and compulsory licensing. *South Centre*, Research Papers 41 [online]. Available from: http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf [Accessed 31 May 2016].

[226] WHO (n.d.) Public health, innovation, intellectual property and trade – Facilitating access to patent information. *WHO* [online]. Available from: http://www.who.int/phi/patent_info/en/ [Accessed 31 May 2016]); WIPO (2012) Patent landscape report on vaccines for selected infectious diseases. *WIPO* [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946_3.pdf [Accessed 19 July 2016]; UNDP (2012) Patent information and transparency: A methodology for patent searches on essential medicines in developing countries. *UNDP* [online]. Available from: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/a-methodology-for-patent-searches-on-essential-medicines-in-deve.html [Accessed 31 May]).

[227] The Medicines Patent Pool maintains a patent database of selected ARVs in certain low and middle income countries (See: Medicines Patent Pool Database (most recently updated in September 2015). Available from: http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/ [Accessed 31 May 2016]). India's patent office publishes lists of pharmaceutical patent applications and grants (See: Ministry of Commerce and Industry India. Controller General of Patents, Designs and Trademarks (lastly updated 2012). Available from: http://ipindia.nic.in/app_Status/granted_Patent_Pharma_01012009_31122011.xls, http://ipindia.nic.in/iponew/Patent_PharmaProduct_2005_06_2009_10.pdf, http://ipindiaonline.gov.in/workingofpatents/ [Accessed at 31 May 2016]). WHO also publishes patent landscape reports—detailed overviews of patent activity in one field—including one on vaccines (see WIPO (2012) Patent Landscape Report on Vaccines for Selected Infectious Diseases. WIPO [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946_3.pdf [Accessed 19 July 2016]). Civil society organizations such as I-MAK have undertaken important patent landscapes of other diseases (see, e.g., Initiative for Medicines Access and Knowledge (I-MAK) (2013) Patent Landscape Report for Pegylated Interferon Alfa 2A and 2B. *I-MAK* [online]. Available from: http://static1.1.sqspcdn.com/static/f/129694/21983308/1361387069633/I-MAK+Patent+Landscape+for [Accessed 31 May 2016]. See also: See Knowledge Ecology International (KEI) (2016) Transparency of patents on medicines and other technologies. *KEI* [online]. Available from: http://keionline.org/node/2478 [Accessed 2 June 2016]. Lawyers Collective (n.d.) Drugs patent status - India. *Lawyers Collective* [online]. Available from: http://www.lawyerscollective.org/drugs-list [Accessed 6 August 2016].

ANNEX 1: COMMENTARIES

The commentaries are presented in the order that they were received.

Jorge Bermudez, Winnie Byanyima and Shiba Phurailatpam

It has been a great honour to have been a part of the UN Secretary-General's High-Level Panel on access to medicines. The Secretary-General (SG) has shown great leadership in recognizing the critical value of remedying the policy incoherence between international human rights and trade rules in the context of access to health technologies. The SG tasked us, building on previous and existing initiatives, with reviewing proposals and making recommendations to remedy this policy incoherence. This means finding ways to ensure access to existing expensive treatments and R&D for new technologies so that the world can fulfil the commitments of the Sustainable Development Goals (SDGs) to leave no one behind.

All countries have pledged to work to meet the SDGs. Furthermore, human rights including the right to life and health are universal irrespective of where a person is born--whether in a rich or poor country. Therefore, the HLP work was to address the needs of all people being denied access to health technologies including lifesaving treatments for communicable diseases, noncommunicable diseases, neglected tropical diseases and rare diseases in low-, middle- and high-income countries. This is important given the lack of R&D for many health conditions affecting or threatening to affect people all over the world and the increasingly unaffordable prices of medicines for diseases such as cancer and hepatitis C in all countries.

We acknowledge the hard work of our fellow Panel members. We also recognize the Secretariat's intensive support, as its staff worked tirelessly from the beginning. As a Panel, we have been able to agree to a number of recommendations that make some steps forward to remedy the incoherence of policies. However, we regret that the panel was not able to reach consensus to acknowledge the systemic failure of the current R&D and access system – based on intellectual property (IP) protection as embodied in the WTO's TRIPS Agreement and aggravated by free trade and investment agreements and treaties - and to elaborate proposals that could more concretely, and in the short, medium and long term, remedy the failed system.

In short, we as a Panel could have and should have been bolder. It is critical to move forward on the far more progressive and visionary proposals on financing, IP and access that seek systemic change in addition to the incremental efforts outlined in the Report. In our opinion the current recommendations are not enough, at this stage, with 15 years of the experience of using the Doha Declaration but most importantly with the evidence and testimonies presented to us by patients from different countries. The report has included encouraging recommendations on transparency and alternative systems of R&D but on the matter of access, we do not believe the recommendations should have been limited to the use of TRIPS flexibilities. The use of TRIPS flexibilities is well known, well documented and well recommended; indeed in the SDGs themselves. Therefore, the three of us have requested to add this personal commentary to the report to expand on what - in our view - should and may still be done.

The Panel received inputs from the Panel's Expert Advisory Committee and over 180 submissions and held public hearings. We have heard, followed and seen real stories of human suffering, due to lack of appropriate therapies or lack of access to existing but unaffordable technologies. Some contributions were not new ideas, and some have been included in previous reports but did not receive sufficient support to implement them. In fact, the mandate of the HLP has raised the highest expectation in people worldwide who see it as the opportunity to recommend solutions that can pave the way forwards to ensure that human rights dictate innovation and access to health technologies for all. Only this way can we truly ensure that no one is left behind by 2030 and beyond.

Yet, despite the evidence we heard from all stakeholders on the lack of adequate public investment in driving the R&D agenda and on the current problems of access to existing lifesaving treatments and health technologies under the present patent regime, the Panel has not been able to move forward on some of the bolder proposals. Below are few examples that we recommend should be taken forward:

First: We support the call for the discussion on a new IP regime for pharmaceutical products which is consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. We support the findings and recommendations of the Global Commission on HIV and the Law in this regard. It is with regret that there was lack of consensus within the Panel on examining proposals to remedy the incoherencies in the human rights and trade frameworks as they relate to the current system of IP and thus the report has no recommendations in this regard. We do not accept the assertion in the Report that any process to renegotiate TRIPS or a new IP system that recognizes the primacy of human rights, may result in the derogation of such rights. We reiterate that on this matter there was neither consensus nor any conclusion of the HLP. *We recommend that this critical recommendation should be pursued in other UN forums.*

Second: The threats of retaliation if governments use or show their intent to use TRIPS flexibilities (as the Report illustrates with Thailand and Colombia, among other cases) calls for recommendations of bold punitive actions against governments making such threats, which are missing in the report. We recommend the following:

All UN member states should, in compliance with prevailing international human rights obligations and TRIPS obligations, reaffirm their commitment to the anti-retaliation principle and sovereignty of WTO Members in complying with TRIPS

as reflected in Article 1.1 of the TRIPS Agreement. Unilateral retaliation against countries using or intending to use TRIPS flexibilities should be deemed a violation of the TRIPS Agreement. We strongly urge the WTO to take immediate and appropriate punitive actions against such violations. We further call for an additional mechanism to be established at the UN Human Rights Council that should receive and investigate complaints (by UN member states, civil society, any other stakeholder or even by the HRC on its own accord) relating to the violation of human rights treaties as a result of trade retaliation (actual or threatened) where countries seek to use TRIPS flexibilities. The HRC should recommend actions to be taken within the framework of human rights treaties as well as include such matters in the Universal Periodic Reviews of UN members.

Third: Countries should be free from pressure when they use TRIPS flexibilities including in deciding and using pro-health patentability criteria. Although the report emphasizes countries' right to implement pro-health patentability criteria, it does not highlight the serious problems that they face when they do so. India is a case in point where pharmaceutical companies challenged Section 3(d) of India's patent law which restricts patents on new uses and new forms of existing medicines, unless in the case of the latter, there is a significant improvement in efficacy. Although the Indian Supreme Court upheld the strict application of this law in favour of the government, pressure from other countries continues in order to change the Indian law. We draw specific attention to the ongoing litigation filed by multiple multinational pharmaceutical companies against the strict patentability criteria and strict patent examination processes in Argentina and Brazil and call for an immediate withdrawal of these cases *and for the ceasing of all such litigation by industry against the use of TRIPS flexibilities.*

Fourth: TRIPS-plus measures in free trade agreements (FTAs) must be halted, reversed and banned. The report acknowledges the continuing limitations of policy space for government action because of TRIPS-plus measures in FTAs, which create further incoherence between human rights and IP protection. However, it needed to go further with strong and bold recommendations to address this incoherence. We recommend that TRIPS-plus measures must be immediately halted, reversed and banned. All new FTAs and those that are under negotiation should exclude TRIPS-plus measures as well as investor-state dispute settlement (ISDS) mechanisms. FTAs already signed must be revised to exclude TRIPS-plus measures and ISDS. We are alarmed at the ongoing negotiations on the Regional Comprehensive Economic Partnership Agreement which involves three key global producers of API and generic medicines (China, India and Thailand) and call on the governments in the RCEP negotiations to immediately remove all TRIPS-plus proposals and ISDS measures relating to health from the negotiations.

Fifth: Governments must be enabled to address access barriers within the current IP system through automatic licensing for essential medicines. Several submissions made detailed proposals on how to address access barriers within the present IP and trade framework, ranging from voluntary approaches to full exemption for patenting for some or all medicines. Yet, in spite of explicit references to the Doha Declaration, primarily voluntary approaches are being recommended. These voluntary approaches are problematic because they are inadequate and not sustainable, and are limited to geographic scope, among other concerns, that is defined by industry. We also need solutions that can provide all governments with options to address access barriers. We believe that the Medicine Patent Pool has a role to play but given the aforementioned limitations of voluntary mechanisms, we do not agree that the solution to the unaffordable prices is expanding the MPP to all diseases.

We recommend that medicines on national lists or on the WHO Model List for Essential Medicines should be exempted from IP protection. This would comply with the legal obligation of States to take measures aimed at the prevention, treatment and control of diseases, ensuring availability, accessibility, acceptability and quality of essential medicines as a core obligation of the right to health; and it is compliant with the TRIPS Agreement. We have repeatedly included in several comments that the UN Secretary-General should engage with the leadership of WTO to request an authoritative interpretation of Articles 27 and 30 of the TRIPS Agreement in order to allow members to exclude essential medicines from patentability. We were initially encouraged by the recommendation in the report that WTO Members adopt effectively automatic compulsory licensing for essential medicines. However, we are now seriously concerned that this recommendation for effectively automatic compulsory licensing have been removed at the last minute due to lack of consensus. **(please see later commentaries on this point).**

While the right to health imposes an immediate obligation to provide access to essential medicines, there is an obligation for the progressive realization of access to all health technologies and along with the immediate and effective use of TRIPS flexibilities by all countries, we also recommend that relevant UN forums and the WTO examine the issue of how IP constraints can be removed from all health technologies while protecting the justifiable rights of inventors.

Sixth: The waiver for Least Developed Countries (LDCs) should be extended.
We recommend that the LDCs' transitions periods be extended further than 2021 and 2033 so that the waiver stays in effect until an LDC country ceases to be in this category of countries. We recommend that all LDCs immediately review their national and regional IP regimes to ensure the full use of these transition periods.

In our view, several of these solutions should be made available in addition to those recommended in the main report.
Finally, the legal and advocacy work of civil society in ensuring the incorporation, use and protection of TRIPS

flexibilities in national and regional legal systems must be supported: The failure to recognize and support the range of successful and critical legal work undertaken by civil society groups in all countries in the actual implementation of TRIPS flexibilities, including use of competition law and patent oppositions, is a major gap in the narrative and the recommendations of the Report. This work is being done in the face of massive human and financial resources limitations and dwindling international funding. Accordingly, we call for UN agencies and other international aid agencies and donors to provide funding, possibly including through the creation of a specific fund, to support the legal and advocacy work of civil society, including the filing of patent oppositions

Moreover, we regret that there are a number of critical issues missing, misrepresented or insufficiently addressed in the report-problems include:

- The emphasis on "**Unavailability of health insurance**" as a reason for lack of access to medicines. This occurs despite numerous explanations that such language implies that insurance coverage leads to access to medicines. This is not correct given that insurance does not protect people from the high cost of medicines nor does it guarantee access to the medicines they need even in high income countries. There is strong evidence that public, social and private insurance use rationing in providing expensive medicines by, for example, allowing prescription of hepatitis C treatment only to patients with certain liver damage.
- Lack of a clear discussion on **access issues as they relate to existing new medicines to treat anti-microbial resistance (AMR)**. In this regard, the prices of new drugs where they do exist as well as delays in their registration in developing and least developed countries are also creating barriers in dealing with AMR in resource constrained settings. We note that for the new TB drugs like bedaquiline and delamanid, their pricing and availability remains a huge challenge in high TB burden countries. Two years after these two drugs have come onto the market, MSF estimates that less than 2% of those who need these treatments can access them while the so-called access pricing remains out of reach for most governments and patients (US $ 1,700 for delamanid through the Global Drug Facility and US $ 3,000 for bedaquiline in middle income countries). We draw particular attention to this dimension of AMR and call on all governments to take necessary legal actions to ensure the availability and affordability of existing treatments for patients who need them.
- Lack of clear reference to industry claims which were sometimes presented in a "factual" manner or as the opinion of the HLP. This includes claims that patents have produced the finances for R&D in medicines, or that the system has delivered the medicines that people need. We advised several times to clarify the language.

It remains a particular regret for us that the Panel's Report could not document or acknowledge much of the evidence placed before us in the testimonies of patients at the London and Johannesburg hearings. We believe those testimonies were the soul of the High-Level Panel's process. It is the brave struggles of patients and communities that demand we take full advantage of the opportunity presented by the High-Level Panel and the interest it has created among those concerned with R&D and access to health technologies, in order to move forward on issues beyond what has been agreed by consensus.

We believe our recommendations presented above are critical to ensure that all people all over the world have access to affordable health technologies they need, that no one is left behind and that no lives should ever be lost because of the price of a medicine.

Andrew Witty

Improving access to medicines for patients and citizens across the world is one of the great challenges of our time. It is an issue of great importance to me. I am proud that GSK has led the independent Access to Medicines Index on each of the four occasions it has been compiled.

Nobody would dispute the need for improvement in both innovation of healthcare technology and access to it. Everyone understands there is much to do. People are being left behind.

That said, advances in medical technologies, and new partnerships and collaborations, have led to a massive increase in life expectancy and a dramatic fall in childhood mortality in recent decades. The past 10-15 years has been a period of unprecedented progress. A diverse portfolio of new models and mechanisms for developing and delivering medicines, vaccines and other healthcare technologies - such as AMCs, PDPs, the Medicines Patent Pool, tiered pricing, and collaborations such as the pharmaceutical industry coalition on NTDs - have delivered extraordinarily fast and impressive results in the range of medicines and vaccines available and in the number of people able to access them.

Novel approaches and partnerships have led to tailored solutions, developed through consensus, to specific challenges and circumstances.

The huge achievements of the current system of healthcare innovation are often ignored or taken for granted. Equally, although many different stakeholders (particularly academia and public and philanthropic funding institutions) contribute significantly, it is often forgotten that almost all of the world's medical technology has come directly from, or with the enormous contribution of, the research-based pharmaceutical, biotechnology and medtech industries. Those contributions have been largely stimulated by incentives underpinned by intellectual property. The approaches and partnerships referenced above all operate within and alongside the IP system.

The Panel was limited both by the narrow, IP-orientated, scope of its mandate and the short time period during which it operated and as a result could only meet a few times as a Panel.

My fellow Panel Members and the Secretariat showed commitment, good intent, diligence, great respect and expertise throughout, and delivered some constructive comment and recommendations. While inevitably, well-trodden subjects such as TRIPS took up a lot of the Panel's time the Report introduces and encourages some new areas of focus. Notably the responsibility of Governments to transparently reconcile their policy choices as they affect access, the role of private sector employers in helping to protect their employees' health, and the scope to explore delinkage approaches in specific areas of market failure such as AMR.

Other recommendations suffer from a lack of rigorous testing, sometimes based on assertion rather than data/evidence, and some are vague, lacking clarity on how they will be progressed – for example, what will the development of a Code of Principles for Biomedical R&D address, and what patent rights would publicly-funded R&D be entitled to? These subjects will need much more exploration. The Panel had neither the time nor capacity to validate evidence submitted to it in these areas.

The Report makes two false or at least highly dubious implicit assumptions which are foundational to some of the narrative and recommendations:

Firstly, that the value (clinical or financial) of an innovation is clear at the time of discovery and patenting. It almost never is.

Second, that national governments will commit, and be able to raise, the very substantial funds that are required to incentivise future innovation. This especially in the context of an R&D Convention, which may explain why this idea, in its grandest form, remains stalled in the international forums where it has been discussed.

These two assumptions are important as they are used to reassure on alternate approaches to the current system, when in fact neither are likely to prove robust or be broadly deliverable.

Finally, the Report makes frequent reference to the range of factors impacting access, particularly in the many parts of the world where there is limited access even where no patents exist and prices are at generic levels. However, due to its narrow mandate and short timeline it does not analyse these other factors in depth nor offer a clear mechanism or process by which they can be addressed. Addressing global access to medicines requires a holistic approach to assess all factors impeding access and their relative importance, followed by practical and tailored solutions which build on what has been shown to work.

Specific Issues of Concern

Compulsory Licensing

I recognize that compulsory licenses can be used legally and that, where they are, fair and efficient compulsory license processes are needed. I also believe that industry and other stakeholders should not overreact to every compulsory license and treat it automatically as a 'no-go area' - they should respond on a case-by-case basis, after careful analysis of the facts.

The Panel could not agree on further evolution of this complex policy space and the Co-chairs correctly reflected this disagreement in the final Report. I fear that any element of automatic use of compulsory licenses for medicines would have significant unintended consequences. The journey from concept to finished medicine can take up to 25 years. If there is significant uncertainty about returns being available for successful, value-adding products at the end of that period, investors and therefore companies would be much less willing to invest the significant levels of funding required to discover, research and develop new medicines. Innovation would be endangered for patients around the world.

Compulsory licenses should be granted in line with the provisions of the TRIPs agreement and the Doha Declaration. They should therefore not be a routine or automatic element of a country's industrial or health policy, and should not generally be used if there are good therapeutic alternatives available at reasonable prices. If a compulsory license, or any other TRIPs flexibility, is to be pursued, it should be preceded by negotiation.

It is also important to acknowledge that the vast majority of the medicines on the WHO Essential Medicines List are not patented, and yet a third of the world's population do not have reliable access to them. For the 2013 list, there were 375 medicines on the list and only around 20 (5-6%) had patents. For the 2015 list, there were 409 medicines on it and only around 34 (8%) had patents. Few, if any, of those 34 are patented in LDCs or in many other poorer countries. Additionally, LDCs are not required to introduce patents for any medicines before the year 2033. This means that IP plays no role in the lack of access for these medicines and these countries, so IP-based ideas such as CLs are extremely unlikely to help.

The TRIPS framework provides countries with a variety of options which can be used as needed. Built on collaborative negotiation and voluntary agreements I believe most situations could be rapidly resolved if they are indeed priorities for the member state. I see no reason for countries to be forced or required to amend the current framework.

Delinkage

The Report states that "Ebola and Zika are a stark reminder of the need for delinkage". In fact the lack of treatments for these outbreaks has nothing to do with the market-driven IP model. The lack of preparedness was caused by many factors, not least of which is that these diseases were not regarded as global health priorities by the WHO or others, as the report acknowledges. There is no evidence that delinkage would have made a difference to readiness for these outbreaks.

Delinkage can play an important role in solving particular problems. In some PDPs for NTDs, it has helped to reduce the costs of development, make products more affordable, and get new products to patients faster.

Similarly, reflecting the unique set of issues around AMR, it is helpful that a new economic model delinks the volume of sales of a new antibacterial from the revenues the company receives.

Delinkage will likely not be appropriate or useful for many therapy areas. Different mechanisms are needed for different problems when they arise - a one-size fits all approach is not optimal, and is potentially damaging to innovation.

Including costs and prices as an aspect of Regulatory Approval

The Report suggests that the costs of developing a medicine should be shared with regulators who approve medicines. The regulatory approval system is based on quality, safety and efficacy and is well-established and well-proven.

Assessment of costs and price should not be part of that process. Not least because the skills of assessment are fundamentally different. Separate processes also maximize transparency of decision making.

Making use of TRIPs Flexibilities and other IP issues

The report overstates the extent of the TRIPS flexibilities. TRIPS does not permit unlimited use of CL or unlimited discretion to determine what is and is not patentable. Countries should consider making use of this framework as necessary and should not be mandated to do so.

Definition of patentability criteria

Patentability must be based on clear, rationale and predictable criteria. The Report proposes that Member States should have the right to define these criteria in the best interests of public health without in any way describing how that is to be judged. This would create complexity and unpredictability for all stakeholders involved in the innovation process.

Patents are granted at the very start of the development process when the impact of the discovery is unclear and when most discoveries are destined to fail. Further complexity in this arena will add no value and require extensive new capacity. It would be helpful to more clearly define the undesirable aspects of 'evergreening' rather than a wholesale change in patenting approach.

Conclusions

The current system is not perfect, but we must be careful about how we go about improving it. It would be wrong and irresponsible to fundamentally disrupt this model without a well-tested alternative ready to replace it. A proper assessment of the unintended negative consequences of proposed change is also crucial in such a highly interconnected policy space. Otherwise we risk undermining recent collaboration, and a loss of momentum in innovation, and as such could jeopardize access for future generations to key innovation.

Maria C. Freire

The High-Level Panel is united in its belief that every human life is valuable and that it is our duty and responsibility to ensure that advances in science and technology support this core tenet. Over the past months the HLP has heard, studied and addressed some of the concerns that have arisen from inconsistencies in policy and practice related to the human right to health and the creation, protection and distribution of health technologies. The wealth of information provided to the HLP and its deliberations demonstrate once again the need for concerted, purposeful action of all involved, including governments, academia, private companies, philanthropy, civil society and patients. The short period of time in which to fulfil the High-Level Panel's remit and its narrow mandate resulted in a report that may provide a platform for further discussion although it does not, and realistically could not, fully delve into the multiple causes for the lack of broad access to medical technologies.

Access to medicines and health technologies is predicated on their being available for use. The report stresses the imperative for medical innovation, without which no new drugs, vaccines, diagnostics, personal protective equipment and other fit-for-purpose medical technologies would exist. However, it does not explore viable new models for innovation that are implementable, financially sustainable or that tap, enhance and coalesce the expertise and know-how of the scientific community worldwide. Specifically, action is required on practical, concrete, achievable goals for medical innovation: ensuring the availability of scientific talent and medical personnel, in-depth understanding of the etiology of disease, implementation of novel trial designs and pre-approved protocols for clinical testing, coherence of disparate regulatory standards for reviewing and approving new technologies, strengthening manufacturing capacity, strategic stockpiling and prompt delivery of medical products. The report acknowledges additional myriad of factors that also limit availability and access, including tariffs, taxes, regulations and protectionist barriers, which are beyond the scope of the High-Level Panel remit. Nonetheless, such matters are critical to understanding why patients are not able to access the medicines they need, including those on the Essential Medicines List that may or may not be patent-protected, and to designing recommendations to overcome these hurdles.

Some of the recommendations proposed herein, while well-intentioned, could have unintended and undesirable consequences. Rather than improving the status quo, they may result in curtailing innovation; as a result, important positive trends to promote better access to public health technologies could stall or be reversed. Such a situation may arise from Recommendation 2.6.1 (b), which states that governments should implement national legislation, based

on the provisions found in the Doha Declaration, that facilitates the issuance of compulsory licenses for legitimate public health needs, particularly with regard to essential medicines. There is no question that governments can and should make full, fair and responsible use of flexibilities under TRIPS, especially when the goal is to address the public health needs of their populations. The long-term effect of this recommendation, however, could be to prompt manufacturers to shy away from developing or producing health technologies that address public health needs and to direct R&D resources to health technologies that, while important for some sub-populations of patients, have little broad public health utility or impact. This potential dissonance should be studied in context, possibly by the independent review body proposed in Recommendation 4.3.2 (a), to ensure a robust, sustainable innovation engine that addresses public health needs.

Recommendation 3.4 (c) calls for negotiations on a binding R&D Convention, focused on public health, including neglected tropical diseases and antimicrobial resistance (AMR), that delinks the costs of research and development from end prices to promote access to good health. The HLP discussed delinking as an important potential tool for innovation and was clear that this mechanism is meant to enhance not supplant other drug development efforts. This is reflected in Recommendation 3.4 (c) where it clearly states that delinkage must complement existing mechanisms.

Without innovation, there will be no new tools for public health needs, new pandemics and AMR. There are already precious few diagnostics, vaccines and medicines that can address these menaces and limited resources to support research into the basic biology that underpins them. It would be unwise to set into motion activities or policies that further choke innovation, placing large populations at risk and contradicting the core principles under which the High-Level Panel was convened. As a society, we must continue the dialog and analysis with urgency, press for realistic, fact-based solutions and build on the momentum provided by the High-Level Panel to ensure that medicines are available and accessible for those who need them.

Ruth Okediji

The United Nations Secretary-General's High-Level Panel on Access to Medicines ("Panel") was convened to address one of the most intractable and morally compelling global issues of our time—lack of access to medicines and other health technologies. It is a challenge of immense proportions, affecting rich, middle-income and poor countries—although the effects fall disproportionately on developing and least developed countries. The Terms of Reference for the Panel explicitly identified policy incoherencies among trade, intellectual property (IP) and human rights as the prism through which to study the problem of lack of access to medicines and health technologies[1].

The Panel received a wealth of contributions[2] that underscore the complexity of the interface among these regimes and that have informed the Panel's findings and recommendations. Unfortunately, important aspects of the Panel's rich discussions—as well as practical steps that governments should consider to improve access—are not reflected in its formal recommendations.

The complex combination of laws, institutions, and firms that regulate the development and distribution of drugs and health technologies has done a great deal of good. Yet, as presently constituted, they have also resulted in significant misalignments between, on one hand, the composition and pricing of the drugs produced and distributed by pharmaceutical firms and, on the other hand, social welfare and human rights. For example, too few resources are devoted to vaccines and medicines to treat diseases common primarily in developing countries, and the prices of treatments that have been developed for those diseases are too high. Partly because of this misalignment, healthy life expectancy in low-income countries is sharply lower than in most industrialized countries. The international community has the scientific, institutional and legal capacity to reduce this inequality—and a moral obligation to do so.

It is true that an immediate goal of the IP system is to incentivize and reward innovation, but this is not its only goal. Intellectual property law is also an important tool to promote the public interest in encouraging investment in innovation which ultimately results in the societal diffusion of new technologies. How effectively the IP system accomplishes these social welfare objectives depends on a mix of factors—some related to the proper design and application of different IP laws, and others related to the regulatory and institutional environment in which IP is deployed—factors which vary across countries and disease categories. The freedom to experiment with initiatives that adapt IP rules to local contexts in light of these differences is essential to reducing gaps in access to medicines and health technologies.

With these general observations in mind, I provide below some additional context and detail regarding broad themes and supporting recommendations in the Panel's Report:

[1] See Annex 4, Terms of Reference: The United Nations Secretary-General's High-Level Panel on Access to Medicines.

[2] The submissions to the HLP contain a wealth of information, insights and possible solutions to the challenge of lack of access to health technologies. These submissions should be catalogued and placed in a database accessible to the public. They are an invaluable source of new and promising initiatives; some of the ideas presented could precipitate formation of new partnerships and catalyze new approaches to various aspects of the global challenge of lack of innovation and access to medicines.

Recommendations to Enhance Innovation and Access to Health Technologies

The Panel discussed at length the limits of the IP system to address emerging threats to global public health, such as anti-microbial resistance, and the failure of these models to induce innovation directed at neglected diseases. I share many of the Panel's concerns, but wish to emphasize four practical tools and regulatory initiatives that governments, nongovernmental organizations and private firms can deploy to address neglected diseases—consistently with human rights, IP and trade treaties.

Coordinating Public Health Information and Responses

Collaboration in gathering and disseminating information concerning emerging public health threats, and coordination in developing initiatives to reduce gaps and redundancies in research and development. Such joint efforts could, for example, have mitigated the recent outbreak of Ebola in West Africa and ameliorate the current threat posed by the Zika virus.

Pricing Variations to Enhance Access to Health Technologies

Create an institutional and regulatory environment to facilitate voluntary pricing practices by pharmaceutical firms. For example, national governments could adjust their rules pertaining to reference pricing and to the exhaustion of patent rights in ways that would facilitate both inter- country and intra-country differential pricing of essential medicines. Such pricing should prioritize increasing the availability of drugs to the poorest victims of neglected diseases.

Similarly, foundations or NGOs could provide modest amounts of funding to induce generic firms to accept originator pharmaceutical firm offers of zero-royalty licenses for the production and distribution of patented drugs targeted for use in least developed countries. To avoid inhibiting voluntary pricing initiatives, any price variations, including price discrimination in favor of low-income countries, should not be targeted by high-income countries as a starting point for their negotiations with pharmaceutical firms.

Filling Gaps Left by Markets and Institutions - Innovation Models Focused on Delinkage

Identify appropriate areas in which the cost of producing health technologies can be separated or "delinked" from the cost to consumers. Delinkage as a supplementary organizing principle is particularly important for innovation in health technologies for neglected tropical diseases, orphan diseases and other diseases for which private markets are insufficiently capitalized or nonexistent. Governments or NGOs could use highly focused allocations of funds to help close the gaps in these markets. Such allocations might include targeted grants, prizes for developing vaccines aimed at specific diseases, advance market commitments for neglected diseases, grants to subsidize the development of new antibiotics (combined with appropriate limitations on deployment of those antibiotics in order to minimize resistance), and tax incentives.

A Regulatory Overlay on National Intellectual Property Regimes

Regulatory overlays that governments might impose on the IP system to incentivize firms to direct resources to diseases in developing countries. Such overlays have previously been used in other policy domains, for example to reduce pollution and increase automobile fuel efficiency. For health technologies, governments could consider two main candidates. First, Pigouvean taxes on pharmaceutical firms in proportion to the degree to which they contribute to the misalignments indicated above. Such taxes could nudge firms to develop R&D portfolios that more closely align with human rights and social welfare goals. Second, requiring all pharmaceutical firms to achieve, within a specified timeframe, a designated score on a "social-responsibility index." This index would be a fraction, the numerator of which would be an objective measure of the firm's contributions to public health (in the developing world); and the denominator of which would be a similarly objective measure of the firm's profits. Ideas like this give important flexibility to pharmaceutical firms that embrace social welfare objectives, enhancing opportunities for realistic "win-win" outcomes.[3]

Recommendations Regarding the TRIPS Agreement

The mandatory minimum standards in the TRIPS Agreement have proven to be especially challenging for developing and least-developed countries. A few points discussed at length by HLP, but not included in the Panel's formal recommendations, merit emphasis.

The Relationship between TRIPS and International Human Rights Law

A commitment to mitigate policy incoherence that adversely impacts innovation and access to medicines must have at its core the recognition that every country has a duty to fulfil its obligations in TRIPS and in international human rights law.[4] UN political and expert bodies have repeatedly reaffirmed that states can satisfy these dual commitments by tailoring IP protection to achieve overarching social and human

[3] As suggested by experts, it would be ideal if the pharmaceutical firms whose businesses would be subject to such a regulation would themselves participate actively in designing and implementing the system. Governments would (a) require transparency with respect to the financial data necessary accurately to measure each firm's profits and (b) support (financially and otherwise) an independent, unbiased consortium that would refine and apply the methodologies necessary to estimate fairly the health benefits generated by the distribution and consumption of particular drugs.

[4] For a comprehensive discussion, see Laurence R. Helfer and Graeme W. Austin, Human Rights and Intellectual Property: Mapping the Global Interface, Cambridge University Press, 2011.

rights objectives[5]. The flexibility mechanisms in TRIPS— such as subject matter exclusions, exceptions and limitations, compulsory licenses, and textual interpretations consistent with the treaty's overarching social welfare objectives—are essential for achieving compatibility between the two sets of international obligations[6]. However, precisely how these dual obligations will be given effect will not look the same across all countries and sectors, and certainly not in the area of public health. Governments thus have flexibility to achieve human rights-consistent outcomes that take account of local particularities[7].

Compulsory Licenses

Countries have the right to authorize and issue compulsory licenses. This right is explicitly safe- guarded in leading intellectual property and trade treaties and in national laws. High-, middle-, and low-income countries have all used compulsory licenses to accomplish important ends, including to reduce prices for patented medicines and health technologies. The TRIPS Agreement prescribes a process in Article 31 that must be followed when a WTO Member exercises this sovereign right. The 2001 Doha Declaration provides additional clarification of the flexibilities countries enjoy in determining the grounds for issuing compulsory licenses consistent with Article 31. Countries should be familiar with the various requirements for conditions in which the use of this tool is both warranted and justified in the TRIPS Agreement.[8] Statutory provisions for compulsory licenses adopted in several high income countries, and that are particularly expedient for public health needs, may offer useful examples of an accelerated process. All stakeholders must engage processes regarding the issuance of compulsory licenses effectively, fairly and legitimately. Moreover, countries are entitled to freedom from all forms of reprisal, whether from public or private sources, when exercising such rights.

Not Just Patents

The Panel's deliberations focused on patent law, and understandably so. But trademarks and copyright can exert monopolistic effects in the market that rival those associated with patents and with a far greater duration. The Report is silent on these issues, but there is much work that should be done to tackle the combined effects of different IP rights and other non-IP factors on the cost, distribution accessibility of medicines and health technologies.

Recommendations to Improve Domestic Regulatory Environments

Least-developed countries too often are treated as passive recipients of health aid or unskilled partners in deliberations about public health and access to medicines. Every country must be ensure that its policies and actions are targeted toward ensuring the right to health. Numerous factors can impede this vitally important goal. A country's failure to invest in the physical well-being of its own people, for example, is as much a violation of human rights, and is as morally objectionable, as is endemic corruption. Our collective silence about insufficient investments in national health systems, and the failure to hold governments accountable for these deficiencies, cannot be easily reconciled with the passionate demands to respect the Doha Declaration or to otherwise discipline the TRIPS Agreement.

Poor regulatory conditions in developing and least-developed countries significantly impede access to health technologies. Governments in these countries should begin *immediately* to tackle the policy, legal and administrative incoherence that exists among various government agencies and public health institutions to achieve these goals. A wide range of important tools could be put in place such as:

- Regulations to streamline domestic distribution channels for medicines and health technologies;
- Targeted customs procedures to facilitate prompt clearance of medicines and health technologies at national borders;
- Establishment of registries of medicines protected under national or regional patent laws to facilitate collective negotiations over price with pharmaceutical firms;
- Tax and other incentives to facilitate local production of medicines and other health technologies;

[5] See, e.g., Patent policy and the human right to science and culture, Report of the Special Rapporteur in the field of cultural rights, UN Doc. A/70/279 (Aug. 4, 2015), para. 4 (prepared by Farida Shaheed) ("Well-designed patent laws and policies play a vital role in encouraging private investment in scientific research and development, making an important contribution to scientific progress and human well-being. In order for the international patent system to continue to serve its fundamental purpose of encouraging innovation and promoting dissemination and transfer of technology, the right balance is required between the rights of technology holders and the rights of technology users for the benefit of society as a whole."); Comm'n on Human Rights, Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, UN Doc. E/CN.4/Sub.2/2001/13 paras. 11-12 (June 27, 2001) (stating that "the balance between public and private interests [in Article 15 of the International Covenant on Economic Social and Cultural Rights (ICESCR) and Article 27 of the Universal Declaration of Human Rights] is one familiar to intellectual property law;" the key question "is where to strike the right balance"); Committee on Economic, Social and Cultural Rights, Statement on Human Rights and Intellectual Property, UN Doc. E/C12/2001/15 (Dec. 14, 2001) (IP "must be balanced with the right to take part in cultural life and to enjoy the benefits of scientific progress and its applications," and that "national and international intellectual property regimes must be consistent with" the obligations in the ICESCR).

[6] See, e.g., Special Rapporteur in the Field of Cultural Rights, The Right to Enjoy the Benefits of Scientific Progress and Its Applications, Human Rights Council, U.N. Doc. A/HRC/20/26 para. 59 (May 14, 2012) (prepared by Farida Shaheed) (emphasizing that TRIPS "flexibilities are important tools to ensure respect for human rights").

[7] Id. at para. 58 (emphasizing the "wide range of policy space given to States" that allow for "different standards of IP protection provided [that] the principles and substantive provisions [of human rights law] are fulfiled") (internal quotations omitted). Much can also be learned from national judicial decisions in which courts have developed a dynamic jurisprudence to discipline overreach in the patent system that draws upon international human rights law, constitutional law and other legal regimes including competition law. See, e.g., Alicia Ely Yamin And Siri Gloppen, Litigating Health Rights: Can Courts Bring More Justice to Health? Harvard University Press, 2011.

[8] Jerome H. Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, 37 Journal of Law, Medicine and Ethics, 247-263 (2009).

- Pooling resources and partnering with other countries and with foundations to invest in R&D targeting specific diseases in their regions. R&D agreements among developing countries could facilitate such an arrangement, and could be a step towards a global R&D Convention.

Conclusion

There is no single cause or solution to the persistent and burgeoning problem of lack of access to medicines and health technologies; but there must be single-mindedness in the global commitment to confront it. The Panel's recommendations respond to problems we know and face today. In considering these recommendations, care must be given not to drive innovation to sub-optimal levels or to unjustly tar all innovators with the same brush.

Developing solutions to the dual problems of lack of access to health technologies and lack of funding for health innovation is the collective responsibility of all countries and stakeholders. The convening of the High-Level Panel is yet another effort to urge the international community to be tenacious in seeking to reconcile great scientific promise and achievement with obdurate political will in support of human development. To this end, the most important collective work still lies ahead.

Jorge Bermudez and Winnie Byanyima

We acknowledge the great work of the Co-chairs and the hard work of the Secretariat to accommodate High-Level Panel members' views in the report. However, this note raises objections to the removal of a critical recommendation from the report because of lack of consensus.

This note reasserts our strong support for the vital recommendation on effectively automatic compulsory licensing for essential medicines that did not make it into the final report while also offering another, stronger recommendation that, we believe, would help countries to effectuate the use of TRIPS flexibilities in the face of the political difficulties faced when issuing compulsory licensing. Both recommendations are TRIPS compliant and legally tenable in the opinion of several legal experts. We encourage countries to examine these recommendations and amend their national or regional IP systems in keeping with these recommendations. These recommendations are critical to meeting the obligations of the right to health while allowing countries to also meet their obligations under the TRIPS Agreement.

Several submissions to the High-Level Panel made detailed proposals on how to address access barriers within the present IP and trade framework, ranging from voluntary approaches to full exemption for patenting for some or all medicines. Yet, in spite of explicit references to the Doha Declaration, primarily voluntary approaches have been recommended. These voluntary approaches are problematic because they are inadequate and not sustainable, and are limited to geographic scope that, among other concerns, is defined by industry. The High-Level Panel was tasked, in our opinion, to consider proposals for bigger, bolder action, and regrettably we have found ourselves unable to move beyond voluntary approaches and the existing WTO framework on IP in our discussions and recommendations regarding access to health technologies.

While the High-Level Panel's report emphasizes that all countries must incorporate and fully use TRIPS flexibilities, economic and political realities and serious power imbalances between developed and developing countries and between countries and the multinational pharmaceutical industry stand in the way of implementing this recommendation. Therefore, we were initially encouraged by the recommendation in the report that WTO Members adopt effectively automatic compulsory licensing for essential medicines. However, we are now constrained to record our dissent to the removal of this recommendation for effectively automatic compulsory licensing at the very last minute.

Views of several members of the Expert Advisory Group confirmed that the term "effectively automatic" is consistent with the letter and spirit of the TRIPS Agreement as long as the recommendation specified that the requirements of Article 31 were to be met. Two-thirds of the members of the High-Level Panel were also of the opinion that such a recommendation was important, timely and legally tenable. Yet, the report only refers to the views of some HLP members by stating that **"***... a sizable minority of Panel Members were not, because of concerns over the potential incompatibility of such measures with the TRIPS Agreement and the unintended consequences that may result from such an approach*". We believe that "incompatibility with TRIPS" is legally incorrect.

Moreover, we do not agree with the reference to "unintended consequences that may result from such an approach". We see this phrase as unnecessary alarm. The HLP was tasked to come up with concrete recommendations in order to remedy the policy incoherence, remove barriers and enhance possibilities to ensure access to lifesaving technologies for those in need. Therefore, we believe that this recommendation should be taken seriously by governments.

Governments should, in the interests of meeting human rights and health objectives, implement a system of compulsory licensing in national and/or regional legislation that is effectively automatic by way of its predictability and implementation provided the requirements in Article 31 of the TRIPS Agreement are adhered to. In particular, in the case of essential medicines, while Article 31(a) of the TRIPS Agreement requires that CLs should be considered on their individual merits, a legal mechanism meeting that requirement may employ identification as an essential medicine as the means through which the individual merits of a licence are determined.

In recognition of the political pressure and extensive litigation brought to bear on countries exercising their right to issue compulsory licenses, we recommend that medicines on national essential medicines lists or on the WHO Model List for Essential Medicines should be exempted from IP protection.

This would comply with the legal obligation of States to take measures aimed at the prevention, treatment and control of diseases, ensuring availability, accessibility, acceptability and quality of essential medicines as a core obligation of the right to health; and it is compliant with the TRIPS Agreement. We have repeatedly included in several comments that the UN Secretary-General should engage with the leadership of WTO to request an authoritative interpretation of Articles 27 and 30 of the TRIPS Agreement in order to allow members to exclude essential medicines from patentability.

While the right to health imposes an immediate obligation to provide access to essential medicines, there is an obligation for the progressive realization of access to all health technologies. Therefore, along with the immediate and effective use of TRIPS flexibilities by all countries, we also recommend that relevant UN forums and the WTO examine the issue of how IP constraints can be removed from all health technologies while protecting the justifiable rights of inventors.

Shiba Phurailatpam

"2033 means death to me." - Babalwa Malgas

At the outset, to Ruth Dreifuss and Festus Gontebanye Mogae the co-chairs of the High-Level Panel, my thanks and admiration at their gracious, respectful and determined handling of their unenviable task of pulling together competing interests and outlooks. To my co-panelists, my great appreciation for their insight, discussions and efforts towards reaching agreement and their patience, particularly those Panel members from whom I had a radically different outlook and assessment of proposals. To the Secretariat, a great debt of gratitude for their hard work and support throughout this process.

The final report of the High-Level Panel makes critical recommendations on new systems for research and development, on transparency and on governance. In terms of access, it also makes important recommendations for the incorporation and use of TRIPS flexibilities by all governments and for provisions in FTAs not to undermine the right to health. These recommendations are important and despite my reservations and concerns detailed below, I have signed the Report in the hope that these are taken forward.

However, our task is not complete in terms of recommendations relating to access to health technologies. The Report should have much more clearly addressed and recommended specific action on the fundamental question of systemic change, on recognising the primacy of human rights over trade and intellectual property rules and for the exploration of a new intellectual property system that prioritises human rights as recommended by the Global Commission on HIV and the Law. The recommendations on access in the report on TRIPS flexibilities, their use, on TRIPS-plus provisions, etc. should have been the starting point of our deliberations at the High-Level Panel and not the end point.

There are critical recommendations on what can and should be done on access to medicines and all health technologies that are detailed in the joint commentary by Winnie Byanyima, Jorge Bermudez and myself.

We must give governments more policy options to work within the existing system. The use of legal tools by governments to ensure affordable generic production and supply must be the rule rather than the exception. I therefore echo the commentary of my co-panelists Winnie Byanyima and Jorge Bermudez on the recommendation that countries should pursue effectively automatic licensing systems for essential medicines which found support with two-thirds of Panel members and was confirmed as legally tenably by several members of the EAG. My commentary strongly endorses that particular recommendation and draws attention to the dire situation of those in need of access to medicines at present that I regret has not been sufficiently addressed in the Report.

Over a decade into the full implementation of the TRIPS Agreement in all WTO developing country members, we are in a situation where a single company can now control the world-wide supply, price and availability of a medicine. This situation has been exacerbated by the increasing frequency of arrangements between patent holding companies and generic companies through voluntary licenses so that even countries where no patents exist or are even applied for are well within the control of patent holding companies. Voluntary licenses whether issued through the Medicines Patent Pool or outside of it are not only undermining access to medicines in middle income countries and but are also creating tensions in the use and implementation of TRIPS flexibilities. The glorious chaos caused by the announcement of Indian generic companies that they could make and supply quality, affordable ARVs across the developing world at a dollar a day is a thing of the past as we witness the new era of restricted, controlled and conditional access to patented medicines.

Bearing the brunt of this new era are middle-income countries that are excluded from voluntary licenses and access programmes, are facing continuous litigation and pressure in their use of TRIPS flexibilities as in the case of Brazil and Argentina and that are part of or negotiating FTAs that feature TRIPS-plus provisions. The situation of middle income countries should have received far greater attention in our Report. The prices of 2nd and 3rd line ARVs in middle-income countries are a sobering reality check on our celebrations for getting 17 million people living with HIV on treatment. "Pharmaceutical companies are selling antiretrovirals to non-African middle-income countries at prices 74–541% higher than African countries with similar gross national incomes." (Ford, Hill, et al; JIAS, 2014). Even as the GDP of countries is being used to justify violations of the right to health by the private sector, countries currently benefiting from licenses, access programmes and external funding are likely to face a challenging future as they graduate low income status.

A band of determined patients and activists stand in the way of this tightening grip of corporate power over medicines. It is my personal regret, that despite my best efforts, the critical legal work of people living with HIV, with hepatitis C, with cancer and the many, many civil society groups and public interest lawyers that work with them is not properly acknowledged or supported in this report. The legal work pursued by these groups have played a critical role in the shaping, implementation and evolution of TRIPS flexibilities as we understand them today; whether it was the competition case brought by the Treatment Action Campaign in South Africa, the DDI case in Thailand that established the standing of public interest groups in patent challenges, the patent opposition work in India, Brazil, Argentina, China, Thailand, etc., the victory of cancer groups in preventing the imposition of patent linkage in India through a litigation filed by MNCs and in successfully arguing for the strict application of Section 3(d) in the Novartis case or the successful Constitutional challenge by people living with HIV in Kenya to an anti-counterfeit legislation that threatened the import of generic medicines. The list is far longer and support for the legal work of public interest groups is critical for the successful use of TRIPS flexibilities.

The context for our work on the High-Level Panel is the 2030 deadline for the achievement of the Sustainable Development Goals. In the lives of individual patients, other dates have greater significance. 2033, Babalwa Malgas, a woman fighting breast cancer in South Africa, discovered is the date on which the patents on trastuzumab expire in South Africa. I recognized so well the desperation, resilience and dignity we heard in her testimony of her fight to access this treatment. She was far more eloquent than I could ever hope to be in highlighting the very real impact of the abusive pricing of patented medicines. Like her, my life too depends on the medicines that we are so hotly debating today not just at the Panel but around the world. Several people who put pressure on the work of the Panel accused it of ignoring the role of health systems in limiting access. In the case of patented medicines - it is my own personal experience and that of the multitude of patients in need of patented medicines - that the cascade of misery that we endure in being pushed from pillar to post, in navigating public and private healthcare systems and complicated health coverage and ultimately facing death or destitution, starts with or is certainly made far worse, by the pricing and restricted availability of those patented medicines.

What the process of the High-Level Panel has shown us is that governments will now have to take the lead in addressing access to existing medicines and health technologies. In a forum with multiple stakeholders - some who benefit from the present system and those that are losing from it - there is unlikely to be consensus on some of the most critical issues. Why would those who benefit from the current form of government regulation of intellectual property seek to change it? It is not a coincidence that articles based on leaked versions of the report focused on seeking to ensure that there was no change to the present system. There was clear evidence in the submissions and testimonies of the limitations of relying primarily on voluntary approaches and of the "punishment" meted out to countries who attempt to implement TRIPS flexibilities. It is, therefore, a disservice to me and the people who need access now to continue with the illusion that most, if not all the problems relating to access can be solved within the status quo.

I thank the UN Secretary-General for giving me the honour of being on this Panel and for recognising that the sharpest tensions around access to medicines are around commercial interests and human rights. We have set out in the joint commentary a pathway on access that can and must be taken forward and I would call on the UN Secretary-General to ensure that this particular aspect of the mandate, of ensuring access to health technologies to patients who need them today, along with the recommendations in the joint commentary is further debated and discussed by governments.

ANNEX 2: HOW THE HIGH-LEVEL PANEL REACHED ITS CONCLUSIONS

United Nations Secretary-General's High-Level Panel on Access to Medicines was comprised of 15 eminent individuals with a deep knowledge and understanding of a broad range of legal, commercial, trade, public health and human rights issues critical to promoting innovation and access to health technologies. The High-Level Panel was co-chaired by former Presidents Ruth Dreifuss of Switzerland and Festus Mogae of Botswana. The work of the High-Level Panel took place in a congenial and cooperative atmosphere with a genuine interest from Panel Members in understanding each other's point of view despite their diverse backgrounds and perspectives. While Panel Members had different points of view on occasion, they all agreed that the High-Level Panel's work was both timely and important in increasing access to health technologies for all.

The High-Level Panel was supported by an Expert Advisory Group consisting of 25 experts. Representatives were drawn from United Nations and multilateral organizations, including the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Industrial Development Organization (UNIDO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Children's Fund (UNICEF), the Office of the United Nations High Commissioner for Human Rights (OHCHR), the United Nations Special Rapporteur on the Right to Health, the Joint United Nations Programme on HIV/AIDS Secretariat (UNAIDS) and United Nations Development Programme (UNDP). Additionally, individual experts were drawn from academia, the private sector and civil society. The Expert Advisory Group was chaired by Justice Michael Kirby, who was also a member of the High-Level Panel.

The High-Level Panel cast its net far and wide, distributing its Call for Contributions to over 6,000 experts from government, civil society, academia and the private sector. The Call for Contributions requested solutions to address the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.

Briefings were held with United Nations Member States and organizations in Geneva and New York and with civil society and private sector stakeholders to raise awareness and strengthen their engagement in the work of the High-Level Panel. A total of 182 contributions were received and are available on the website of the High-Level Panel.

The High-Level Panel builds upon previous work, notably by WHO, the Human Rights Council, Special Rapporteurs on the Right to Health, the United Nations General Assembly, the trilateral cooperation between WHO, WTO and WIPO, as well as the work of numerous initiatives taken by public-private partnerships and product development partnerships. In addition to relying on existing literature, inputs from the Expert Advisory Group were provided through background papers produced at the request of the High-Level Panel and submissions by United Nations entities and international organizations, including OHCHR, UNIDO, WHO, WIPO and WTO. In March 2016, Hearings and Global Dialogues took place in London, United Kingdom, and Johannesburg, South Africa. The London Hearing and Dialogue was undertaken in partnership with The Lancet and the Centre for Commercial Law Studies, Queen Mary University of London. The Johannesburg Hearing and Dialogue was co-hosted by the Department of Health, Republic of South Africa. During the Hearings, the High-Level Panel engaged with contributors, experts and government representatives. The Global Dialogues broadened the conversation with contributors, government representatives, the private sector, academia, civil society and patient groups. The Global Dialogues were webcast and are available on the website of the High-Level Panel. A total of 1,355 people participated in Global Dialogues either in person or via webcast.

Following the Hearings and Global Dialogues, in order to develop its finding, recommendations and report, the High-Level Panel held three face to face meetings and two meetings via teleconference. Extensive email exchanges also took place, sharing reactions, comments and proposed amendments among members of the High-Level Panel, in order to reach the maximum level of consensus in finalizing the report.

This report of the High-Level Panel draws extensively upon the contributions, Hearings and Global Dialogues that were used to inform meetings of the High-Level Panel and its Expert Advisory Group. The contributions were invaluable to provide the evidence that informs the contents and recommendations of this report. The High-Level Panel would like to express profound gratitude to all those who contributed to this process.

ANNEX 3: THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

The United Nations Secretary-General's High-Level Panel on Innovation and Access to Health Technologies (High-Level Panel on Access to Medicines for short, also High-Level Panel) was comprised of 15 eminent individuals with a deep knowledge and understanding of a broad range of human rights, legal, commercial, trade and public health issues critical to promoting innovation and access to health technologies.

Co-chairs of the High-Level Panel

Festus Mogae

Ruth Dreifuss

Members of the High-Level Panel

Awn Al-Khasawneh

Celso Amorim

Jorge Bermudez

Winnie Byanyima

Maria C. Freire

Sakiko Fukuda-Parr

Kinga Göncz

Yusuf Hamied

Michael Kirby

Malebona Precious Matsoso

Ruth Okediji

Shiba Phurailatpam

Andrew Witty

At a few meetings when members of the High-Level Panel were unable to participate in person, they were represented by nominated members of the Expert Advisory Group. In this way, Winnie Byanyima was on occasion represented by Mogha Kamal-Yanni, Yusuf Hamied was represented by Denis Broun and Andrew Witty was represented by David Rosenberg.

ANNEX 4: TERMS OF REFERENCE: THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

Recognizing the interdependence of health and development and in line with the recently adopted 2030 Agenda for Development and the Sustainable Development Goals, the United Nations Secretary-General has convened a High-Level Panel on Access to Medicines. The High-Level Panel and its Expert Advisory Group has the following Terms of Reference:

1. Millions of people remain left behind when it comes to accessing medicines and health technologies that can ensure their health and well-being. Failure to reduce the costs of patented medicines is resulting in millions of people being denied access to lifesaving treatments for communicable diseases like HIV, TB, Malaria and viral hepatitis, noncommunicable diseases (NCDs), NTDs and rare diseases. This failure is affecting governments and individuals in all low-, middle- and high- income countries, where budgets are being stretched to capacity by treatment costs.

2. In 2012, the Global Commission on HIV and the Law, an independent body of eminent persons tasked by the Programme Coordinating Board of the Joint United Nations Programme on HIV/AIDS (UNAIDS) with interrogating the relationship between legal responses, human rights and HIV, concluded that a growing body of international trade law is hindering the right to health of millions and that new solutions are needed to incentivize innovation and increase access to treatment.

3. Consistent with the findings and recommendations of the Global Commission on HIV and the Law, and in line with the aspirations articulated in his synthesis report on the post-2015 development agenda and the recently adopted Sustainable Development Goals, the United Nations Secretary-General Ban Ki-moon convening a High-Level Panel on innovation and access to health technologies. The overall scope of the High-Level Panel is to review and assess proposals and recommend solutions to remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies that is impeding access and the right to health for millions.

4. The High-Level Panel comprises of 15 eminent and respected individuals with expert knowledge and understanding of the broad range of trade, public health, human rights and legal issues associated with innovation of and access to health technologies. Panel members include innovators, leaders of the pharmaceutical industry, public health, human rights and international law experts, civil society and government officials.

5. The work of the High-Level Panel builds upon previous and existing initiatives, notably by the World Health Organization (WHO); these include resolutions of the World Health Assembly, work of the Human Rights Council and various Special Rapporteurs on the Right to Health and the United Nations General Assembly that have aimed to achieve a better balance of issues of intellectual property, human rights and increased access to health technologies.

6. The High-Level Panel will solicit and assess proposals, based on objective criteria, for solutions which remedy the policy incoherence between international trade rules and international human rights law. The Panel will conclude its work with a report including evidence-based and implementable recommendations that aim to achieve a better balance of human rights, public health, international trade and sustainable development objectives of United Nations Member States in the context of expanding access to health technologies. More specifically, the High-Level Panel will:

   6.1 The High-Level Panel will review and assess proposals for their potential to improve health technologies innovation and access and make recommendations that:
   a) remedy the policy incoherence between international human rights law and trade rules in the context of access to health technologies; and
   b) achieve a better balance of the justifiable rights of inventors, the right to health and sustainable development.

   6.2 Hold public hearings that facilitate multi-stakeholder dialogues involving technical experts, patient groups, civil society, governments and industry – to broaden the consultation on the proposals.

   6.3 Rely on existing materials in the public domain and request additional research on issues relevant to its enquiry.

   6.4 Make evidence-based and actionable recommendations to the Secretary-General and other relevant stakeholders on remedying the policy incoherence between international human rights law and trade rules in the context of access to health technologies.

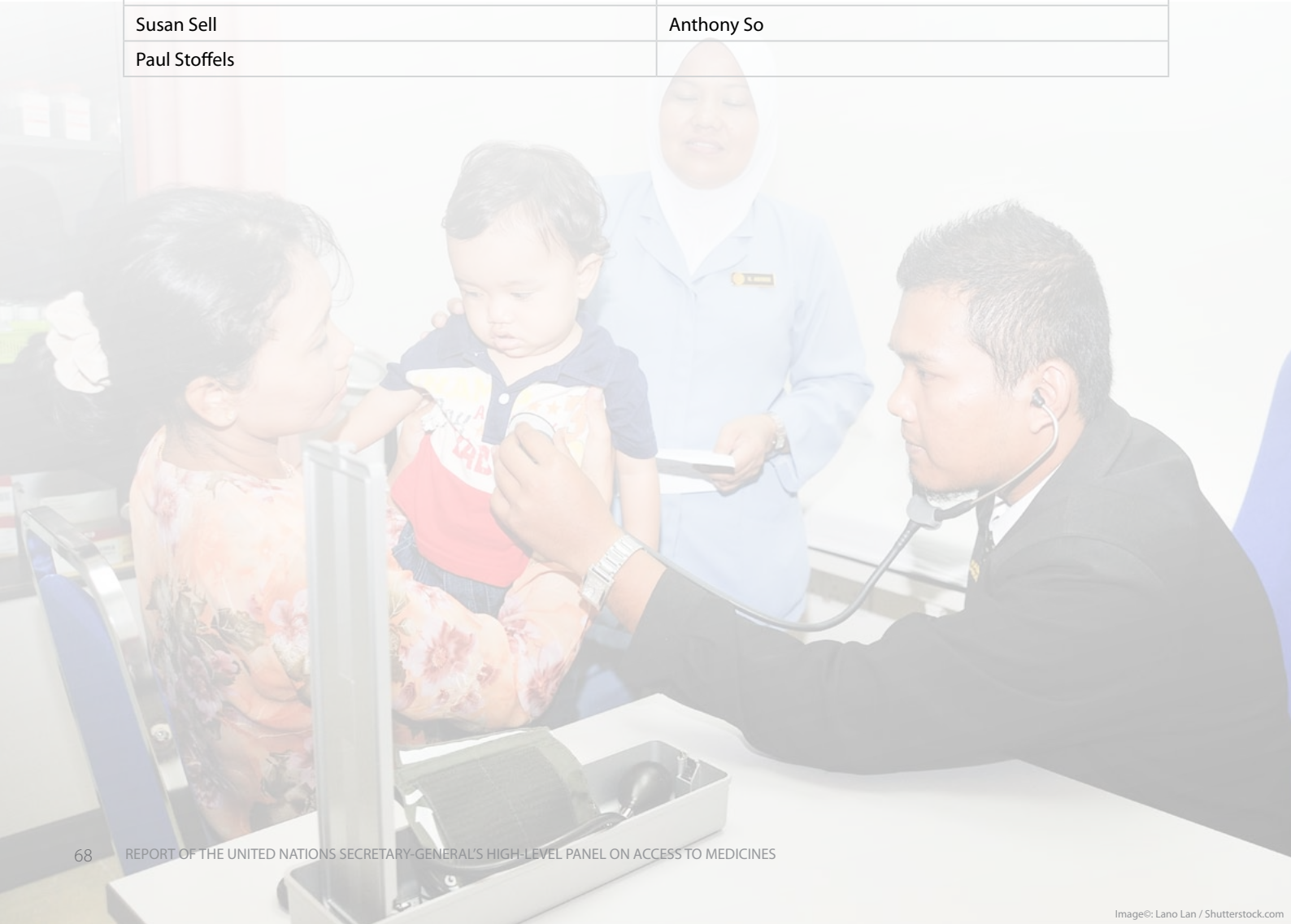
   6.5 Serve as a platform for mobilizing stakeholders on the issues examined by the High-Level Panel and contribute to discussions in other relevant forums, including the High-Level Meeting on HIV/AIDS in 2016.

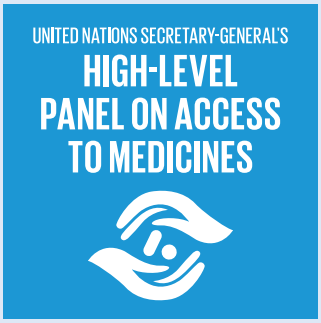
7. The work of the Panel is supported by an Expert Advisory Group assembled to provide technical support to the High-Level Panel. The High-Level Panel and its Expert Advisory Group is supported by a Secretariat based at the United Nations Development Programme in New York. The Secretariat will also work with the Secretariat of UNAIDS.

8. The Expert Advisory Group comprises of experts drawn from the public and private sector, academia, professional and civil society organizations, including people living with HIV, serving in their private capacity. It includes senior technical staff from relevant United Nations and international organizations, including WHO, the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Industrial Development Organization (UNIDO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Children's Fund (UNICEF), the Office of the United Nations High Commissioner for Human Rights (OHCHR), the United Nations Special Rapporteur on the Right to Health, the UNAIDS Secretariat and UNDP. More specifically, the Expert Advisory Panel will:
   - Review and provide inputs into the draft technical documents prepared for consideration by the High-Level Panel, including the final report.
   - Provide inputs in assessing proposals received for review by the High-Level Panel.
   - Participate in, provide technical support and interact with the High-Level Panel during the multi-stakeholder public hearings to review and discuss the shortlisted proposals.
   - Provide other inputs as requested by the High-Level Panel.
9. The Panel will provide periodic progress reports and submit its final report to the Secretary-General by June 2016. The Secretary-General will make the report available to the General Assembly and undertake further action as appropriate.

ANNEX 5: THE EXPERT ADVISORY GROUP

Chairperson Michael Kirby	
Institutional Representatives	
Organisation	**Representative**
OHCHR	Lynn Gentile
UNCTAD	Christoph Spennemann
UNICEF	Francisco Blanco
UNIDO	Alastair West
WHO	Nata Menabde
WIPO	Thomas Bombelles
WTO	Antony Taubman
United Nations Special Rapporteur on the Right to Health	Dainius Pūras
Individual Representatives	
Frederick M. Abbott	Manica Balasegaram
Denis Broun	Carlos Correa
Maria Lorena Di Giano	Richard Elliott
Dominique Foray	Renuka Gadde
Anand Grover	Atsuko Hirooka
Mohga Kamal-Yanni	Suresh Kumar
Suerie Moon	David Rosenberg
Susan Sell	Anthony So
Paul Stoffels	





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