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Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health

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Abstract: Access to medicines is the lynchpin to realizing a range of human rights, public health and development imperatives. However, without strong policy action to increase access to affordable medicines, there is little hope of achieving the Sustainable Development Goals or of realizing the human right to health. Access to medicines is a fundamental element of the right to health, and the majority of states are bound by core obligations in this regard. Accordingly, states must ensure that this critical human rights, public health and development interest is appropriately prioritized against inadequate resource allocations and competing private or trade interests. This is an imperative which we have argued should have framed the deliberations of the UN High Level Panel on Access to Medicines, convened to propose solutions to the "policy incoherence" between international human rights, trade rules and public health that is impeding access to medicines and the right to health for millions. In this article we explore interpretations in international human rights law regarding state duties towards medicines that should have guided these deliberations, and which were presented by the first author in a submission to the panel. We argue that at least two clear right to health duties support the High Level Panel's recommendations: (1) the duty to prevent unreasonably high costs for medicines from denying large segments of the population their rights to health; and (2) the core obligation to provide essential medicines. Consequently, we explore three areas of action implied by these duties: (1) consistent implementation of human rights impact assessment; (2) institutionalizing the Agreement on Trade-Related Intellectual Property Rights (TRIPS) flexibilities in law and policy; (3) making permanent the waiver of TRIPS for least developed countries (LDC), and waiving the application of TRIPS to essential medicines in low and middle-income countries. Finally, we assess the extent to which the recommendations made by the Panel's final report comply with these duties and accordingly with the right to health.

Keywords: human rights law; access to medicine; high-level panel; UN

1. Introduction—Reducing Policy Incoherence between Human Rights and Trade

Access to affordable medicine is the lynchpin to realizing a range of human rights, public health and development imperatives. This is why essential medicines are understood as a core obligation of states under the right to health [1]; why medicines are recognized as a fundamental building block of health care systems capable of providing universal health coverage [2]; and why medicines features prominently within Sustainable Development Goal (SDG) 3 on health [3]. Yet, "essential medicines remain unaffordable and insufficiently available in developing countries" ([3], p. 53). While generic medicine policies are broadly recognized as a key policy intervention to control health budgets and

make medicines more affordable ([4], p. 156), the policy space that countries have to provide affordable medicines is bound sometimes wholesale by trade rules around intellectual property rights.

This "policy incoherence" between human rights and intellectual property rights is a primary motivator for the establishment by United Nations Secretary-General Ban Ki-moon of the High-Level Panel (HLP) on Access to Medicines. The panel was given the mandate "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" ([5], p. 3). Convened in November 2015 and with a final report issued in September 2016, the Panel has worked on an unusually truncated timeline in order to produce solutions to the global drug gap. In December 2015, the Panel called for public submissions to inform its deliberations, augmented by two global dialogues in March 2016 in London and Johannesburg. This article reflects on the Panel's 2016 report and expands on the first author's public submission to the HLP process and attendance at the London hearing. We first explore the impact of trade-related intellectual property rights on access to medicines and the right to health. We then consider what international law and the right to health in particular offer to resolve policy incoherence between these two areas of law. We consider various means of implementing the right to health in this domain. We close with an assessment of how the HLP report's recommendations responded to this area of legal conflict in light of the right to health duties identified in this paper.

2. The Agreement on Trade-Related Intellectual Property Rights

The introduction of the Agreement on Trade-Related Intellectual Property Rights (TRIPS) in 1995 conferred unprecedented exclusive rights to pharmaceutical patent holders. The monopolistic pricing that resulted saw sometimes dramatic increases in drug prices, as in Malaysia where drug prices increased by 28 per cent per year between 1996 and 2005 ([6], p. 689). The use of flexibilities in TRIPS is an important mechanism to ensure that high prices resulting from exclusive patenting rights do not negatively impact public health imperatives. The flexibilities in TRIPS are provisions that enable policy-makers to limit intellectual property rights in order to protect social welfare and public health, including by accessing cheaper drugs. TRIPS flexibilities include compulsory licenses (where governments manufacture or import generics under strict limitations) and parallel imports (where governments import lower priced patented medicines) ([7], p. 3). Yet the use of TRIPS flexibilities continues to attract litigation, drug removals, trade sanctions and economic and diplomatic pressures. At the same time, TRIPS flexibilities are limited and eradicated in free trade agreements, and the global movement of generic medicines through international borders is obstructed under measures to eradicate counterfeit medicines. Global access to affordable medicines is under more not less threat and without effective action at the international level it is unlikely that the SDGs on health or indeed the right to health will be realized.

2.1. Which Countries Are Affected by Conflicts Between Human Rights and Trade Treaties?

The majority of states globally hold duties under the right to health and trade-related intellectual property rights. For example, the International Covenant on Economic, Social and Cultural Rights (ICESCR) had been ratified by 164 states as of 25 February 2016—approximately two thirds of all states globally [8]. At the same time, 162 states globally are members of the WTO [9]. The overlaps between these domains are extensive: at least 133 states that have ratified the ICESCR are also members of the WTO. Yet the overlap is far greater than these figures suggest: WTO members that have not ratified the ICESCR will certainly be bound by health rights in article 24.1 of the Convention on the Rights of the Child, which with 196 ratifications has an effective universality (applicable in almost every country save for the USA), albeit that its rights and duties only apply to children. Irrespective of the precise figures the conclusion is clear: most states globally must balance right to health duties with trade-related intellectual property duties, and this has practical implications for how decision-makers at various levels should interpret and implement these duties.

2.2. Applying a Principle of Systemic Integration to Assure Respect for Human Rights

The imperative to balance duties under competing international legal regimes is addressed in a 2006 International Law Commission (ILC) report exploring the problems created by fragmented legal regimes in international law [10]. The report emphasizes that no specialized regime, including the WTO, operates outside of international law ([10], para. 192). The report argues for application of the principle of systemic integration so as to link functional areas to a deeper normative idea in international law, so that the "common good of humankind [is] not reducible to the good of any particular institution or regime" ([10], para. 480, emphasis added). The report argues that two specific areas of international law offer support in this regard: first, the hierarchically superior norms within international law (such as jus cogens/peremptory norms and obligations ergo omnes/duties owed to all), and second, the Vienna Convention on the Law of Treaties (VCLT) which offers customary rules for international treaty interpretation.

The first author has previously explored the implications of both areas of international law for balancing right to health duties with trade-related intellectual property rights [11], the primary observations of which are reproduced below. The first author's submission to the Panel suggested that the following observations from this research provide important guidance to its deliberations:

(1) While current definitions of international law's hierarchically superior norms (such as peremptory norms and obligations ergo omnes) do not specify the right to health, they do collectively prohibit gross violations of any rights (including health), and place reasonable limits on all human conduct (including trade) to protect human health and life. In any event, access to medicines is explicitly demarcated as a core obligation under the right to health, and this should elevate access to medicines into a hierarchically superior norm within international human rights law. The priority of a right to medicines does not suggest that it automatically "trumps" competing interests. However, the prioritized nature of this right provides an important governing principle for the type of balancing mechanisms between public and private interests that the High Level Panel (HLP) should propose accordingly.

(2) The right to health offers an important framework for interpreting intellectual property rights contained in TRIPS and other multilateral and bilateral agreements. That such treaties should be interpreted in this fashion is supported by article 31 of the VCLT [12], which specifies that treaties must be interpreted in good faith according to the ordinary meaning of treaty terms in their context and in the light of a treaty's object and purpose ([12], art. 31.1). Adjudicators can ascertain treaty context, inter alia from "any relevant rules of international law applicable between the parties" ([12], art. 31.3.c). Article 31.3.c thus supports using ICESCR as a relevant rule of international law applicable between state parties in interpreting trade-related intellectual property rights. As such, article 31.3.c is the clearest textual avenue within international law for ensuring "systemic integration" between human rights and trade rules when adjudicative bodies (including the HLP) assess potential conflicts.

3. International Human Rights Law and Access to Medicines

International human rights law is increasingly explicit regarding the human rights duties imposed on states in relation to medicines, essential or otherwise, and their implications for other legal duties.

3.1. Access to Medicines as a Core Obligation under the Right to Health

The right to health in article 12 of the ICESCR has been interpreted by the United Nations Committee on Economic, Social and Cultural Rights (CESCR) to place prioritized duties on states regarding essential medicines [1]. In General Comment 14 on the Right to the Highest Attainable Standard of Physical and Mental Health, the Committee underscores the importance of state duties towards essential medicines in a number of domains.

First, the Committee indicates that the essential elements of the right to health include ensuring sufficient availability of functioning "public health and health-care facilities, goods and services" including "essential drugs, as defined by the WHO Action Program on Essential Drugs" ([1], para. 12.a). Second, the Committee locates essential medicines within core obligations under the right to health. In General Comment 14, the Committee indicates that core obligations under the right to health include providing "essential drugs, as from time to time defined under the WHO Action Program on Essential Drugs" ([1], para. 43.d). The Committee is explicit about the significance of a core obligation. While all other duties under the ICESCR are subject to progressive realization within maximum available resources, "a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are nonderogable" ([1], para. 47).

Whatever the strength of these duties, the implication holds that a state's core obligations have a temporal and substantive priority over other human rights duties and indeed over duties under other legal regimes.

3.2. Balancing Core Obligations with Other Legal Duties

These implications are made explicit in the Committee's General Comment No. 17 [13]. Here the Committee makes it clear that intellectual property rights are not to be confused with the human right to benefit from the protection of moral or material interests resulting from any scientific production protected in ICESCR article 15.1.c:

> "In contrast to human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, often with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person" ([13], para. 2).

When it comes to balancing duties under other rights in the ICESCR, the CESCR is clear that "private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration" ([13], para. 35). More concretely this means that states should ensure that their legal regimes to protect author's interest "constitute no impediment to their ability to comply with their core obligations" including specifically those under the right to health ([13], para. 35). The Committee goes on to emphasize that:

> "Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines . . . from undermining the rights of large segments of the population to health . . . " ([13], para. 35, emphasis added).

We believe that this explicit interpretation of a state's duties to balance core obligations to provide essential medicines and author's rights provides a crucial foundation for the High Level Panel's recommendations in this domain.

While CESCR general comments do not constitute binding law, they do constitute authoritative interpretations of the ICESCR. Moreover, state consensus on the fundamental nature of duties towards medicines within the right to health is reflected in a series of UN General Assembly resolutions issued since 2001 recognizing that "access to medicines is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" ([14], para. 2; see also [15], para. 1). Certainly these interpretations provide important framing principles for the HLP as it deliberated solutions to the global drug gap that adequately respect the realization of core obligations under the right to health.

4. Implementing Right to Health Duties towards Medicines

What are the concrete actions that should flow from core obligations to provide essential medicines and duties towards medicines more generally? The analysis above outlines at least two clear duties that could have underpinned the HLP's considerations: (1) the duty to prevent unreasonably high costs for medicines from denying large segments of the population their rights to health; and (2) the core obligation to provide essential and other medicines. We suggest that these two duties provide the foundation for at least three primary areas of action: (1) consistent implementation of human rights impact assessment (HRIA) before adopting law and policies affecting access to medicines; (2) institutionalizing TRIPS flexibilities in law and policy; and (3) making permanent the waiver of TRIPS for least developed countries (LDC) and waiving TRIPS for essential medicines in low and middle-income countries.

4.1. Human Rights Impact Assessment (HRIA)

State duties not to obstruct access to affordable medicines extend to when, how and whether they enter into legal regimes or agreements imposing intellectual property rights. HRIA provides a practical mechanism for policy makers to predict and mitigate the health and human rights consequences of intellectual property agreements in international trade agreements on the price and accessibility of medicines [11]. HRIA is a relatively recent idea and practice that has drawn significantly from extant advances in the longstanding fields of health and social impact assessments [11]. In essence, an HRIA requires policy makers to gather evidence of potential impacts of trade-related intellectual property rights on people's access to essential medicines and to measure same against right to health duties in this regard, amending future intellectual property rights laws accordingly. While these kinds of impact assessment are often intended for use by policy-makers, they are also often very effectively used by civil society and academic researchers to gather evidence on policy impacts for use in advocacy campaigns or scholarship ([7], p. 4).

There is very strong support for the contention that states should institutionalize the use of HRIA when entering into and implementing agreements on intellectual property rights:

(1) In General Comment 14 the Committee is explicit that it is a violation of the right to health to fail "to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations" ([1], para. 50).
(2) In General Comment 17 the Committee specifically argues that when entering agreements on intellectual property rights, states should undertake human rights impact assessments before adopting and after implementing such legislation ([13], para. 35).
(3) The Committee and two other treaty-monitoring committees have consistently called on countries to conduct assessments of the effect of international trade rules on the right to health and medicines [16–20].
(4) Olivier De Schutter, the former UN Special Rapporteur on the Right to Food, has argued that HRIA is in fact a human rights legal obligation and that all States should "prepare human rights impact assessment prior to the conclusion of trade and investment agreements" ([21], p. 5).

The first author has, with Gillian MacNaughton, developed an HRIA specifically focused on trade related intellectual property rights and the right to health that provides a user-friendly framework for such assessments [7]. An HRIA would provide clear evidence of how proposed intellectual property rights would impact drug affordability and access, allowing states to mitigate this impact in a number of ways (such as not adopting the rights and implementing measures to ensure affordability). HRIA are a practical and feasible way to ensure policy coherence between the right to health and intellectual property rights duties, and to ensure that population health is not unduly sacrificed to trade or commercial imperatives.

4.2. Institutionalization of TRIPS Flexibilities

As indicated above, TRIPS flexibilities give policy makers much needed space to limit the extent to which intellectual property rights increase prices and decrease access to medicines, essential or otherwise. In this regard there is very clear and explicit political support for using TRIPS flexibilities to advance access to affordable medicines:

(1) The Doha Declaration explicitly endorses the right of WTO members to protect public health and promote access to medicines for all, and to use TRIPS flexibilities to the full to do so ([22], para. 4).
(2) Numerous UN General Assembly resolutions urge states to promote access to medicines for all, including through using to the full TRIPS flexibilities [14,15].
(3) SDG 3.8 calls on states to achieve universal health coverage that includes access to safe, effective, quality and affordable essential medicines and vaccines for all. SDG 3.b proposes an explicit means of implementation for this goal that states "provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all" ([23], p. 17).

This political consensus underscores the importance of TRIPS flexibilities in realizing the right to medicines not simply as a public health but human rights imperative. This interpretation is strongly supported by Anand Grover's contention as former UN Special Rapporteur on the Right to Health that states hold a right to health duty to use TRIPS flexibilities. Grover argued that duties to protect the right to health extend to ensuring "developing countries and LDCs should review their laws and policies and consider whether they have made full use of TRIPS flexibilities or included TRIPS-plus measures, and if necessary consider amending their laws and policies to make full use of the flexibilities" ([15], para. 97).

These interpretations would support the High Level Panel making strong explicit recommendations that explicitly specify the TRIPS flexibilities in question and that recommend:

(1) That states institutionalize the use of TRIPS flexibilities in domestic law and policy
(2) That states consistently and effectively use these mechanisms to advance access to affordable medicines
(3) That TRIPS flexibilities are protected from erosion in free trade and other agreements
(4) That the imposition of TRIPS plus intellectual property rights that restrict TRIPS flexibilities violate the right to health

4.3. Making Permanent the LDC Waiver from TRIPS and Restricting the Application of TRIPS to Essential Medicines in LMIC

TRIPS flexibilities are a necessary but insufficient solution to resolving the way that trade-related intellectual property rights contribute to restricting large segments of the population from accessing affordable medicines. In this regard the HLP could have considered two interrelated mechanisms: a permanent waiver of TRIPS's pharmaceutical patents to LDC and a permanent waiver of the application of TRIPS to essential medicines in low and middle-income countries.

TRIPS originally waived the application of TRIPS in to LDC until 2005 (TRIPS, article 66.1). This transition period has been extended twice after requests by the LDC Group, first to 2013 and then to 2021 [24]. With regard to medicines, the Doha Declaration asked the TRIPS Council to extend the waiver for LDC to apply TRIPS to pharmaceuticals until 2016 ([22], para. 7). The TRIPS Council approved this request. In November 2015 the TRIPS Council extended the transition period for pharmaceutical patents until 1 January 2033 or when a country ceases to be an LDC if that happens before 2033. The Council also waived obligations regarding mailbox applications and exclusive marketing rights that would otherwise apply to LDC [25]. This waiver applies only to LDC albeit

that it extends to all pharmaceuticals. The 2012 UN Commission on HIV and the Law makes the more ambitious proposal that TRIPS is urgently suspended for essential medicines for low and middle-income countries while the UN Secretary General convenes a new body to recommend a new intellectual property regime for drugs ([26], pp. 86–87).

The UN Commission's proposal underscores the appointment of the High-Level Panel, and should be adopted and expanded in the following ways:

(1) The HLP should recommend that the WTO waiver of TRIPS to LDC to 2021 and the waiver of TRIPS to pharmaceuticals in LDC to 2033 be made permanent.
(2) The HLP should recommend that this waiver be extended to permanently suspend the application of TRIPS to essential medicines in low and middle-income countries generally.

While the latter recommendations are relatively bold reforms of the current system that are likely to be highly contested, we argue that these reforms are nonetheless feasible: *First*, a permanent waiver is unlikely to be inconsistent with WTO non-discrimination rules requiring that WTO members be treated equally and without special favours, given that the current system clearly views existing waivers and transition periods for LDC and pharmaceutical patents as legitimate under WTO rules [24,25]. *Second*, expanding access to affordable medicines offers exponential population health benefits. This amplification effect is suggested by how the expansion of antiretrovirals in low and middle-income countries has resulted in significant reductions in AIDS-related morbidity and mortality and major improvements in AIDS prevention [27]. For example, greatly reduced drug prices combined with international funding has seen access to these medicines increase from under a thousand people in 2000 to over 15 million people [27]. The public health impact of expanded access to antiretroviral medicines has been dramatic: there were 34 percent fewer AIDS-related deaths in Sub-Saharan Africa in 2014 than in 2000 and a 41 percent drop in infections in Sub-Saharan Africa since 2000 ([27], pp. 8–10). *Third*, even the most radical of these proposals poses little threat to the current system of innovation that drives the development of new medicines. This conclusion is strongly supported in the 2006 report of the WHO Commission on Intellectual Property, Innovation and Health which held that where "the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market" ([28], p. 34). To this extent, suspensions of TRIPS in LDC or for essential medicines in low and middle incomes countries are unlikely to significantly affect innovation in ways that are disproportionate to the human rights needs that doing so would meet.

5. Assessing the Panel's Final Report Against these Recommendations

The HLP's final report issued in September 2016 is strongly framed around the right to health and several of its recommendations are similar to those made in this article and the earlier submission to the Panel. Indeed, the framing imperative of the right to health is apparent in the very first paragraph of the report, which references the multiple international treaties that protect the right to health and acknowledges that medicines are core obligations under this right: "Despite the presence of rights and the commitments 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" ([29], p. 12). Moreover, the report recognizes that state duties to respect, protect and fulfil the right to health "requires taking proactive measures to promote public health" ([29], p. 6).

Yet when it came to recognizing the implications of these right to health duties for trade and intellectual property rights, the Panel was more circumspect. Certainly the Panel recognized the fundamental difference between human rights and intellectual property rights in similar terms to General Comment 17. The Report states:

> "Human rights are fundamental, universal entitlements that people inherently acquire by virtue of their birth. In comparison, 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" ([29], p. 20).

Elsewhere the primacy of human rights is more explicitly articulated, with the report recognizing that "[t]he very nature of fundamental human rights requires that they outweigh private interests under national law" ([29], p. 24). Yet in the panel's view, resolving incoherence between these sets of rights should ensure not simply that trade and intellectual property rights do not "impede access to needed health technologies that sustain health, well-being and life," but that human rights and public health do not impede innovation in new medicines ([29], p. 20). On the one hand this position recognizes long standing industry concerns that reduced drug costs will negatively impact innovation of new medicines. Yet the Panel is to be commended for rejecting the contention that TRIPS flexibilities are capable of posing such threats.

The panel recommends that "WTO members should commit themselves, at the highest possible 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" ([29], p. 27), and that this means making "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" ([29], p. 9). In particular states should "adopt and implement legislation that facilitates the issuance of compulsory licenses" ([29], p. 27). These are important recommendations that reinforce prior policies supporting the use of TRIPS flexibilities to advance public health and human rights imperatives, such as the World Health Organization's 2008 Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health [28], and the 2016 Sustainable Development Goals on health [30]. Yet these recommendations also go no further than these prior policies, losing an important opportunity to progress beyond the status quo on strategies to increase access to medicines.

The report also makes strong recommendations regarding the use of impact assessment similar to those made in this article. Thus, the report recognizes that when it comes to TRIPS-plus commitments "[f]ailure to conduct robust impact assessments before concluding such agreements is tantamount to a neglect of state duties to safeguard the right to health" ([29], p. 25). In the Panel's view, "human rights and public health impact assessment 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" ([29], p. 34). The specific recommendation in this regard is that:

> "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" ([29], p. 28).

Yet the Panel's implicit line in the sand regarding the limitations of the primacy of human rights over trade comes in the absence of bold recommendations capable of altering the current system of trade rights. There is nothing in the report analogous to our recommendation that TRIPS be waived permanently for LDC and suspended permanently for essential medicines in low and middle-income countries. The closest the Panel came was a recommendation that governments issue automatic compulsory licenses, removed from the final report because the Panel could not reach consensus on this issue ([29], p. 23). Commentaries from dissenting panellists from civil society decried this removal, arguing that "the panel could have and should have been bolder," including by exempting essential medicines from IP protection and extending the waiver for LDC ([29], pp. 53–54). As one panellist put it:

> "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" ([29], p. 28).

6. Conclusions

We have argued that at least two clear right to health duties should have guided the HLP's recommendations: the duty to prevent unreasonably high costs for medicines from denying large segments of the population their rights to health and the core obligation to provide essential medicines. In turn we suggest that these duties imply three areas of action: consistent implementation of human rights impact assessment; institutionalizing TRIPS flexibilities in law and policy; and making permanent the waiver of TRIPS for LDCs, and waiving the application of TRIPS to essential medicines in low and middle-income countries.

The HLP is to be commended for its willingness to make recommendations similar to these, and for other innovative proposals, including recommendations to initiate negotiation on a global research and development treaty to delink R&D costs from end prices, and to create independent review bodies to assess progress on drug innovation and access. These recommendations offer important strategies that may incrementally advance access to medicines on the ground. Yet the Panel declined to propose deep reform of the current system, preferring instead 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" ([29], pp. 19–20). Indeed, when it comes to accessing existing medicines, the Panel relied almost entirely on expanding usage of existing (and admittedly crucial) safeguards like TRIPS flexibilities and human rights impact assessment. In this light it is hard not to see the Panel's reluctance as a missed opportunity to significantly move the needle on international access to medicines policies far beyond pragmatic and limited incrementalism towards reforms more realistically capable of broadening access to medicines on the ground for those who need them most.

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