

HIGH LEVEL PANEL ON ACCESS TO MEDICINES



CONTRIBUTION OF THE UNITED NATIONS OFFICE OF THE HIGH COMMISSIONER FOR HUMAN RIGHTS

I. Introduction

1. The Office of the United Nations High Commissioner for Human Rights (OHCHR) welcomes the establishment of the High Level Panel on Access to Medicines (the Panel), with its mandate 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”.
2. Given the scope of this mandate, the High Level Panel has a genuinely unprecedented opportunity to examine, in considerable depth, the applicable norms and standards of law as well as trends in how they are translated into policy. The realisation of key global commitments on health, including those set out in the Sustainable Development Goals,¹ depends on unlocking access to medicines for the millions throughout the world for whom it is only infrequently attainable, if at all. Crucially, the work of the Panel would provide comprehensive and authoritative guidance on how to address challenges encountered across many ongoing initiatives to improve access to medicines and promote the right to health.
3. This paper elaborates on the issues raised in OHCHR’s intervention during the briefing to Member States in Geneva on 1st February 2016. The approach will be to identify the human rights involved, to outline the intellectual property and trade law questions which are of relevance to the Panel’s inquiry and to propose perspectives that may be of use in considering solutions.

II. The human rights framework

A. The right to the highest attainable standard of physical and mental health

4. The right of everyone to the highest attainable standard of physical and mental health is recognised by several human rights instruments,² including the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights (ICESCR)³ and the Convention on the Rights of the Child.⁴ It is a justiciable right, interdependent with and indivisible from other human rights, and access to medicines and health technologies is a fundamental building block of the right to health.⁵
5. As well as recognising the right to health, article 12 of the ICESCR identifies a number of mandatory measures that States should take in order to achieve its full realisation. These include measures necessary for the reduction of the stillbirth and infant mortality rates, and for the healthy development of the child, the prevention, treatment and control of epidemic, endemic and occupational diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness.⁶
6. The strong normative framework for the right to health has benefited from the authoritative interpretation of experts in the field, most notably the Special Rapporteur on the right to

¹ Goal 3(b) aims to “support research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration which affirms the right of developing countries to use to the full the provisions in the TRIPS agreement regarding flexibilities to protect public health and, in particular, provide access to medicines for all”.

² See articles 10(h), 11(f), 11(2), 12 and 14(2) (b) of the Convention on the Elimination of All Forms of Discrimination against Women, article 28 of the International Convention on the Protection of Migrant Workers and their Families, article 5(e) (iv) of the Convention on the Elimination of All forms of Racial Discrimination and article 25 of the Convention on the Rights of Persons with Disabilities.

³ Article 12.

⁴ Article 24.

⁵ See Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (2009), A/HRC/11/12, para. 10.

⁶ Article 12(2).

health⁷ and the Committee on Economic, Social and Cultural Rights (CESCR), charged with monitoring its implementation under the ICESCR.

7. The Committee has provided extensive guidance on the content of the right to health. As to character, the right to health contains freedoms, such as autonomy over one's health and body, and entitlements, including a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.⁸ It is an inclusive right, covering access to health care as well as the many factors which affect its enjoyment – the underlying determinants of health.⁹
8. A human rights framework for realising the right to health calls for national governments to ensure that health facilities, goods and services are available in sufficient quantity, and are physically accessible and affordable on the basis of non-discrimination. Health facilities, goods and services are also required to be gender-sensitive and culturally appropriate, scientifically and medically appropriate, of good quality, and respectful of medical ethics.
9. According to the Special Rapporteur on the right to health, access to medicines has four dimensions: medicines must be accessible in all parts of the country; they must be affordable to all, including those living in poverty; they must be accessible without discrimination on any of the prohibited grounds; and reliable information about medicines must be accessible to patients and health professionals in order to facilitate informed decision-making.¹⁰
10. All relevant stakeholders should be able to participate, through transparent processes, in the development and implementation of health policies. Health authorities and other duty bearers should be held accountable for meeting human rights obligations in the area of public health, including through the possibility of seeking effective remedies via complaints mechanisms or other avenues for redress.
11. While the right to health is subject to progressive realisation, the obligation to ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups, is an immediate one.¹¹ Moreover, certain obligations are non-derogable, and these include the provision of essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs, the equitable distribution of all health facilities, goods and services and the adoption and implementation of a national public health strategy and plan of action on the basis of epidemiological evidence.¹²

B. The right to enjoy the benefits of scientific progress and its applications ("the right to science")

12. The Committee on the Theoretical Bases of Human Rights, convened by the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1947 to work on developing the fundamental concepts underpinning the draft Universal Declaration of Human Rights, acknowledged a "right to share in progress", characterised by "the right to full access to the enjoyment of the technical and cultural achievements of civilization."¹³ Subsequently, the Universal Declaration on Bioethics and Human Rights, which states that "benefits arising from

⁷ The full title of this position is Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

⁸ CESCR, General comment No. 14 (2000) on the right to the highest attainable standard of physical and mental health, para. 8.

⁹ CESCR, General comment No. 14 (2000), para. 11.

¹⁰ Report of the Special Rapporteur on the right to health (2006), A/61/338, para. 49.

¹¹ CESCR, General comment No. 14 (2000), para. 30.

¹² See CESCR, General comment No. 14 (2000), para. 43.

¹³ UNESCO Committee on the Philosophic Principles of Human Rights, *The grounds of an international declaration of Human Rights*, in *Human Rights: Comments and Interpretations*, Appendix II p.14, para. 15.

scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries" acknowledged access to quality health care as being one such benefit.¹⁴ The right to enjoy the benefits of scientific progress is now well-established under international human rights law, and is recognised in the Universal Declaration of Human Rights (article 27(1)) and the ICESCR (article 15(1) (b)).

13. Arguably the most important element of this right is that innovations essential for a life with dignity should be accessible to everyone, in particular marginalised populations.¹⁵ According to the Special Rapporteur in the field of cultural rights, the normative content of the right includes access to the benefits of science by everyone, without discrimination; opportunities for all to contribute to the scientific enterprise and the freedom indispensable for scientific research; the participation of individuals and communities in decision-making; and an enabling environment fostering the conservation, development and diffusion of science and technology.¹⁶ She noted that States should ensure that the benefits of science are physically available and economically affordable to all on an equal footing, and that the non-discrimination dimension calls for the removal of both *de jure* and *de facto* barriers.¹⁷ In particular, positive steps must be taken to ensure non-discriminatory access to scientific information, processes and products for marginalised populations, such as people living in poverty and persons with disabilities, as well as the elderly, women and children.
14. With regard to permissible limitations on the right to science, the Special Rapporteur emphasised that restrictions must pursue a legitimate aim, be compatible with the nature of this right and be strictly necessary for the promotion of the general welfare in a democratic society, in accordance with article 4 of ICESCR. All limitations on the right should, in any event, be proportionate.¹⁸

C. The right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author

15. The right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author is protected by article 15(1) (c) of the ICESCR. Article 27 (2) of the Universal Declaration of Human Rights is similarly worded, providing for "the right to the protection" of these interests. In General comment No. 17, CESCR elaborated on the normative content of this right. Adequate legislation and regulations, as well as effective administrative, judicial or other appropriate remedies, for the protection of the moral and material interests of authors must be available within the jurisdiction of the States parties (availability); administrative, judicial or other appropriate remedies for the protection of the moral and material interests resulting from scientific, literary or artistic productions must be accessible to all authors (accessibility);¹⁹ and procedures for the protection of the moral and material interests of authors should be administered competently and expeditiously by judges and other relevant authorities (quality of protection).²⁰
16. The Committee distinguished between intellectual property rights and the right protected under article 15 (1)(c) in the following terms: "Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity,

¹⁴ UNESCO Universal Declaration on Bioethics and Human Rights (2005), article 15.

¹⁵ Report of the Special Rapporteur in the field of cultural rights (2012), A/HRC/20/26, para. 29.

¹⁶ Report of the Special Rapporteur in the field of cultural rights (2012), A/HRC/20/26, para. 25.

¹⁷ Report of the Special Rapporteur in the field of cultural rights (2012), A/HRC/20/26, paras. 30-31.

¹⁸ Report of the Special Rapporteur in the field of cultural rights (2012), A/HRC/20/26, para. 41.

¹⁹ See para. 18(b) for a more detailed overview of the overlapping dimensions of accessibility.

²⁰ CESCR, General comment No. 17 (2005) on 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 is the author, para. 18.

encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole".²¹ The Committee added that intellectual property rights are generally of a temporary nature and may be subject to revocation, licensing or assignment, whereas human rights are inalienable.²² The scope of protection provided for in the ICESCR does not necessarily coincide with intellectual property rights, as recognised under domestic law or international agreements.²³

17. In interpreting article 15(1)(c), States should balance the protection of this right with the other rights recognised in the ICESCR, ensuring that the private interests of authors are not unduly favoured and that the public interest in enjoying broad access to their work is given due consideration.²⁴ In this regard, States have a duty to prevent unreasonably high costs for access to medicines and to avoid undermining the rights of large segments of the population to health, food and education (the last two rights being determinants of health as well as independent rights).²⁵ Finally, article 15(1)(c) entails a number of core obligations, including the duty of States to: take legislative and other necessary steps to ensure the effective protection of the moral and material interests of authors;²⁶ respect and protect the basic material interests of authors resulting from their scientific, literary or artistic productions;²⁷ and strike an adequate balance between the effective protection of the moral and material interests of authors and States parties' obligations in relation to the rights to food, health and education, as well as other rights.²⁸

III. Barriers to access to medicines

A. Human rights violations

18. The violation of health and health-related human rights accounts for many barriers to access to medicines. In addition to the high cost of many essential medicines, barriers include socio-economic factors such as poverty, discrimination and inequality, as well as laws, policies and other structural factors which restrict access to medicines.

B. Excessive intellectual property protection measures

19. An exhaustive treatment of intellectual property protections (including those implemented through trade and investment agreements) is not envisaged in this paper. Nevertheless, the findings of the Global Commission on HIV and the Law with regard to their impact on access to medicines are instructive and bear repeating.²⁹ While the Commission addressed access to medicines mainly in the context of HIV, identical considerations apply in respect of other pharmaceutical products:

"A growing body of international trade law and the over-reach of intellectual property (IP) protections are impeding the production and distribution of low-cost generic drugs. IP protection is supposed to provide an incentive for innovation but experience has shown that the current laws are failing to promote innovation that serves the medical needs of the poor. The fallout from these regulations—in particular the TRIPS framework—has exposed the central role of excessive IP protections in

²¹ CESCR, General comment No. 17, para. 1.

²² CESCR, General comment No. 17, para. 2.

²³ CESCR, General comment No. 17, para. 2.

²⁴ CESCR, General comment No. 17, para. 35.

²⁵ CESCR, General comment No. 17, para. 35.

²⁶ CESCR, General comment No. 17, para. 39(a).

²⁷ CESCR, General comment No. 17, para. 39(c).

²⁸ CESCR, General comment No. 17, para. 39(e).

²⁹ Global Commission on HIV and the Law, *HIV and the Law: Risks, Rights & Health*, 2012.

*exacerbating the lack of access to HIV treatment and other essential medicines. The situation is most dire in low- and middle-income countries but reverberates through high-income countries as well. Provisions allowing some low- and middle-income countries exceptions to and relaxations of these rules could help alleviate the crisis, but pressure against their use is substantial. A small number of countries have been able to take advantage of the few international legal flexibilities that exist.*³⁰

20. The disproportionate protection of intellectual property rights has two important consequences, among others: it limits the policy space available to governments to take the measures necessary to protect the right to health and restricts access to medicines by expanding monopolies, maintaining high prices for longer periods of time and delaying the availability of generic medicines. As indicated by the Special Rapporteur in the field of cultural rights, "innovations essential for a life with dignity should be accessible to everyone, and potential implications of scientific advances likely to have a significant impact on human rights require attention".³¹ Predominant policy trends in this area have, however, led to the doling out (on terms which the disadvantaged in society lack the power or wherewithal to negotiate) of benefits that should be shared by all. The impact of this well-entrenched dynamic which pits those with means and influence against the poor and vulnerable is profoundly negative.

C. Trade and investment agreements

21. Historically, trade agreements tended to focus narrowly on tariffs; now, within the context of the World Trade Organisation and, increasingly, in bilateral and regional Free Trade agreements their coverage has expanded to services, intellectual property, investment and many other issues. A fairly recent trend has been the rise of "mega-regionals", sprawling modern pacts which have altered the landscape of trade and investment in unprecedented ways. These pacts "impose fundamental changes to countries' legal, judicial and regulatory frameworks, without input or accountability through democratic institutions".³²
22. The right of stakeholders to participate in policy formulation, implementation, monitoring and evaluation is a central tenet of a human rights-based approach to health.³³ The Special Rapporteur in the field of cultural rights noted "an apparent democratic deficit in international policymaking on copyright". Providing as examples the Anti-Counterfeiting Trade Agreement and the Trans-Pacific Partnership, she referred to "the tendency for trade negotiations to be conducted amid great secrecy, with substantial corporate participation but without an equivalent participation of elected officials and other public interest voices".³⁴ The Special Rapporteur on the right to health has stated that "the rights to information and to participate in the decision-making process are essential for the enjoyment of the right to health" and that "those elements of the right to health framework are undermined when international investment agreements are negotiated and concluded in secrecy". He reiterated that "affected communities should be able to participate in negotiations".³⁵
23. The encroachment of entitlements arising from trade and investment agreements on the margin of appreciation reserved for governments to determine how best to meet their obligations is, in itself, highly problematic, particularly from a human rights standpoint. Furthermore, it is often reinforced by formidable investor protections, an important pillar of

³⁰ Global Commission on HIV and the Law, *HIV and the Law: Risks, Rights & Health*, 2012, p.8.

³¹ Report of the Special Rapporteur in the field of cultural rights (2015), A/70/279, para. 3.

³² See Report of the Independent Expert on the promotion of a democratic and equitable international order (2015), /AHRC/30/44, para 12.

³³ CESCR, General comment No. 14 (2000), para. 11.

³⁴ Report of the Special Rapporteur in the field of cultural rights (2014), A/HRC/28/57, para. 19.

³⁵ Report of the Special Rapporteur on the right to health (2014), A/69/299, para. 50.

which is the investor-State dispute settlement system. Although there are several different forums, one difficulty which most dispute settlement systems have in common is the power vested in private individuals, who have not been vetted through any democratic process, to make decisions limiting States' margin of appreciation. The available jurisprudence points strongly to the inference that these decisions are made without recourse to human rights or any other principles and standards that place the public interest, at the very least, on a comparable footing.³⁶

24. As further noted by the Special Rapporteur on the right to health, the "mere threat of onerous and expensive litigation may create a chilling effect where States would refrain from formulating... [protective] policies in the first place".³⁷ Thus, as with excessive intellectual property protections, trade and investment agreements (have the potential to) limit the ability of governments to act in the public interest as corporate interests are, effectively, elevated above human rights obligations and afforded stronger protection. Moreover, the aggressive protection of investor rights is able to literally hold governments to ransom if they take public health or other measures which negatively affect corporate profits or other interests.

IV. Denial of access to medicines as a human rights violation

25. The World Health Organisation estimates that non-communicable diseases (NCDs) accounted for almost 70% of the global mortality rate in 2012 (38 million deaths),³⁸ and NCDs continue to be a leading cause of preventable morbidity and associated disability.³⁹ According to the WHO's Global Status Report on Non-communicable Diseases, more than 40% of these deaths were premature, occurring at below 70 years of age.⁴⁰ The Joint United Nations Programme on HIV/AIDS (UNAIDS) reports that, as of the end of 2014, 1.2 million people had died from AIDS-related illnesses, 36.9 million people globally were living with HIV and there had been 2 million new HIV infections. Only 15.8 million people had access to antiretroviral therapy as of June 2015.⁴¹ For these and other diseases, access to medicines is, therefore, critical to the health response at all levels, including at the global and national levels. As noted elsewhere in this paper, it is an indispensable element of the right to health; its denial is a violation of this right.
26. Given that medicines are essential for health and life, affordability and availability are also important applications of the right to enjoy the benefits of scientific progress. Where the protection of the rights of inventors operates as a limitation on its enjoyment, this protection becomes incompatible with the right to science, it is clearly disproportionate and is detrimental to the general welfare. Similarly, the poor balancing of intellectual property rights and other rights such as health, and the failure to ensure an enabling environment for the diffusion of pharmaceutical products is contrary to the right to science.
27. The International Covenant on Civil and Political Rights (ICCPR)⁴² and the Universal Declaration of Human Rights⁴³ both guarantee the right to life. The Human Rights Committee, which monitors the implementation of the Covenant, has described the right to life as "the supreme right from which no derogation is permitted even in time of public emergency which

³⁶ See, for example, *Compañía de Aguas del Aconquija S.A. and Vivendi Universal (formerly Compagnie Générale des Eaux) v. Argentine Republic* (Case No. ARB/97/3); *Vattenfall AB and others v. Federal Republic of Germany* (ICSID Case No. ARB/12/12); *Railroad Development Corporation v. Republic of Guatemala*, ICSID Case No. ARB/07/23.

³⁷ Report of the Special Rapporteur on the right to health (2014), A/HRC/26/31, para. 58.

³⁸ WHO, Global Status Report on Non-communicable Diseases, 2014, p.xi.

³⁹ Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Treatment of NCDs (January 2012), para. 15.

⁴⁰ WHO, Global Status Report on Non-communicable Diseases, 2014, p.9.

⁴¹ See UNAIDS Factsheet 2015: <http://www.unaids.org/en/resources/campaigns/HowAIDSchangedeverything/factsheet>

⁴² Article 6.

⁴³ Article 3.

threatens the life of the nation” and has indicated that it should not be interpreted narrowly.⁴⁴ State parties are bound, under article 2 of the ICCPR “to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status”.⁴⁵

28. Article 2 further provides that “[w]here not already provided for by existing legislative or other measures, each State Party ... undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the present Covenant, to adopt such laws or other measures as may be necessary to give effect to the rights recognized in the present Covenant”.⁴⁶ In relation to positive measures to protect the right to life, the Committee considered that it would be “desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics”. Where the lack of access to medicines leads to death, it is clear that a *prima facie* violation of the right to life has occurred.
29. Article 7 of the ICCPR and article 5 of the Universal Declaration of Human Rights proscribe cruel, inhuman or degrading treatment or punishment. The denial of access to medicines is considered here in the context of access to pain relief medication, in respect of which the following observations are apposite: “Chronic pain is one of the most significant causes of suffering and disability worldwide, and is a common symptom of both communicable...and noncommunicable... diseases, as well as accidents. Pain has a profound impact on quality of life and can have physical, psychological, and social consequences. It can lead to reduced mobility and a consequent loss of strength, compromise the immune system, and interfere with a person’s ability to eat, concentrate, sleep, and interact with others. People who live with chronic pain have been found to be four times more likely to suffer from depression or anxiety than people who are not in pain. The physical and psychological effects of chronic pain can also negatively influence the course of disease and indirectly influence disease outcomes by reducing treatment adherence.”⁴⁷
30. The Special Rapporteur on the right to health and the Special Rapporteur on torture⁴⁸ have both emphasised that the failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel, inhuman and degrading treatment. The Special Rapporteurs stressed that “Governments must guarantee essential medicines – which include...opioid analgesics – as part of their minimum core obligations under the right to health, and take measures to protect people under their jurisdiction from inhuman and degrading treatment”.⁴⁹ In his report to the United Nations Human Rights Council in 2009, the Special Rapporteur on torture expressed the view that “the *de facto* denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment”.⁵⁰ Underlining the importance of an integrated approach to the care of older persons, CESCR has stated that such measures should be based on “attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity”.⁵¹

⁴⁴ Human Rights Committee, General comment No. 6 (1982) on the right to life, para. 1.

⁴⁵ Article 2(1).

⁴⁶ Article 2(2).

⁴⁷ D. Lohman, J.J. Amon, “Evaluating a Human Rights-Based Advocacy Approach to Expanding Access to Pain Medicines and Palliative Care: Global Advocacy and Case Studies from India, Kenya, and Ukraine”, *Health and Human Rights Journal*. December 2015, Vol. 17, No. 2, p. 150. See also Human Rights Watch, *“Please do not make us suffer anymore”: Access to pain treatment as a human right* (New York: Human Rights Watch, 2009).

⁴⁸ The full title of this mandate is the Special Rapporteur on Torture and Other Cruel, Inhuman and Degrading Treatment or Punishment.

⁴⁹ Joint letter to the Chairperson of the fifty-second session of the Commission on Narcotic Drugs, 2008, p. 4. See also Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment (2013), A/HRC/22/53, paras. 54-56.

⁵⁰ Report of the Special Rapporteur on torture (2009), A/HRC/10/44, para. 72.

⁵¹ CESCR, General comment No. 14 (2000), para. 25.

V. Redressing the balance: human rights-based interventions

31. States have committed, by treaty, to upholding human rights and have reaffirmed these engagements in political declarations covering a range of issues. They have also adopted bilateral and multilateral trade and investment agreements requiring policy-making in areas where tensions with human rights obligations inevitably arise. It is our submission that policy incoherence in public health, trade and intellectual property law and human rights is rooted in a failure to accord human rights norms their rightful place in the legal order.
32. The international community of nations has repeatedly recognised the status of human rights as a value of the highest order deserving of robust protection. The preamble to the Charter of the United Nations refers to the affirmation of "faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women"⁵² while the Universal Declaration of Human Rights acknowledges that "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world".⁵³
33. The World Conference on Human Rights observed that "human rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of Governments".⁵⁴ More recently, on the adoption of the Sustainable Development Goals, States asserted "the importance of the Universal Declaration of Human Rights, as well as other international instruments relating to human rights and international law" and underscored "the responsibilities of all States, in conformity with the Charter of the United Nations, to respect, protect and promote human rights and fundamental freedoms for all, without distinction of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, disability or other status".⁵⁵ Numerous political declarations are in similar vein, and the conclusion, taking into account the absence of any serious assertions to the contrary, must be that consensus on the status of human rights has been established beyond question. In light of this, the domestic protection of human rights should be raised to a level commensurate with their internationally recognised status as foundational norms; accordingly, three human rights interventions are put forward as elements of a solution to policy incoherence.

A. Human rights due diligence

34. In elaborating international legal frameworks and agreements, including bilateral and multilateral arrangements regulating trade and intellectual property, States should ensure that any commitments arising from these do not compromise their ability to respect, protect and fulfil the right to health and other rights whose application has an impact on access to medicines in any way. Corporate entitlements should not receive more protection than human rights, and investor-State disputes should not be subject to adjudication in a system that lacks transparency, has little or no regard for human rights or the public good, and from which no appeal is possible.
35. States should not enter into commitments which may have an adverse impact on the enjoyment of human rights, and human rights-based impact assessments should be conducted both during and after the negotiations through an inclusive and transparent process allowing for the full participation of stakeholders.⁵⁶ As recommended by the Special Rapporteur on the right to health (albeit in a particular national context), "before any trade agreement is finalized assessments [should] identify the likely impact of the agreement on

⁵² Preamble, para.2.

⁵³ Preamble, para. 1.

⁵⁴ Vienna Declaration and Programme of Action (1993), para. 1.

⁵⁵ Outcome document, Transforming our world: the 2030 Agenda for Sustainable Development (2015), General Assembly resolution A/RES/70/1, para. 19.

⁵⁶ Report of the Special Rapporteur on the right to health (2005), E/CN.4/2005/51/Add.3, para. 50.

the enjoyment of the right to health, including access to essential medicines and health care, especially of those living in poverty".⁵⁷

B. Universal health coverage

36. The International Labour Organisation (ILO) estimates that in excess of 90 per cent of the population living in low-income countries has no right to health coverage and that, globally, about 39 per cent of the population lacks coverage. Even where coverage is provided for, it often fails to meet the requirements of availability and affordability, resulting in limited health benefits and high out-of-pocket expenditure.⁵⁸
37. From a human rights perspective, universal health coverage calls, at its most basic level, for the creation of conditions by the State as principal duty bearer which would assure to every person all appropriate medical service and medical attention in the event of need.⁵⁹ Thus, universal health coverage should take account not only of an expansion of coverage for basic preventative, curative and rehabilitative health services but also of equitable access, for every person, to the full complement of necessary and appropriate health care and services.
38. The normative framework applicable to universal health coverage is well-developed. In addition to the recognition of the right to health as outlined above, the ICESCR recognises the right to "social security, including social insurance"⁶⁰ while the Universal Declaration of Human Rights recognises it "in the event of ... sickness, disability ... or other lack of livelihood in circumstances beyond his control".⁶¹ The work of the ILO in this area has contributed significantly to defining universal health coverage and to demonstrating the links between social protection and the right to health.⁶²
39. Interventions aimed at achieving universal health coverage could include:
 - (a) the identification of gaps in coverage;
 - (b) the allocation of resources sufficient to roll out a policy on universal health coverage;
 - (c) integrating universal health coverage into the legislative and policy framework to ensure the recognition and protection of the right to health;
 - (d) as part of measures envisaged in paragraph (c) above, the development and implementation of a policy on universal health coverage incorporating the following components:
 - (i) The cost of the service should be met collectively by regular periodical payments which may take the form of social insurance contributions or of taxes, or of both.⁶³
 - (ii) Health care services should cover all members of the community, whether or not they are gainfully occupied.⁶⁴

⁵⁷ Report of the Special Rapporteur on the right to health (2005), E/CN.4/2005/51/Add.3, para. 50.

⁵⁸ ILO, World Social Protection Report 2014-2015, p. 99.

⁵⁹ ICESCR, article 12.2(d).

⁶⁰ ICESCR, article 9.

⁶¹ Universal Declaration of Human Rights, article 25(1).

⁶² See, for example: the Social Security (Minimum Standards) Convention, 1952 (No. 102), the Medical Care and Sickness Benefits Convention, 1969 (No. 130) and Medical Care and Sickness Benefits Recommendation (No. 134) and the Social Protection Floors Recommendation, 2012 (No. 202).

⁶³ ILO Medical Care Recommendation, 1944 (No. 69), para. 4.

⁶⁴ ILO Medical Care Recommendation, 1944 (No. 69), para. 8.

- (iii) Complete preventive and curative care should be constantly available, rationally organised and, so far as possible, co-ordinated with general health services.⁶⁵
- (iv) Complete preventive and curative care should be available at any time and place to all members of the community covered by the service, on the same conditions, without any hindrance or barrier of an administrative, financial or political nature, or otherwise unrelated to their health.⁶⁶
- (v) The expeditious establishment or strengthening of social protection floors comprising basic social security guarantees. The guarantees should ensure at a minimum that, over the life cycle, all in need have access to essential health care and to basic income security which together secure effective access to goods and services defined as necessary at the national level.⁶⁷ The social protection floors should include access to a nationally defined set of goods and services, constituting essential health care, including maternity care that meets the criteria of availability, accessibility, acceptability and quality.⁶⁸

C. Enabling environment

40. Laws and policies determine, to a great extent, the realisation of health and health-related rights, including access to medicines. Consequently, measures to ensure an enabling legal and policy environment are of paramount importance and should have as an objective the repeal, rescission or amendment of laws and policies that restrict the realisation of these rights, and the enactment of positive laws and policies to support them.⁶⁹ In the context of access to medicines, interventions could include:
- (a) a detailed assessment, through transparent and participatory processes, of the legal and policy framework to establish the extent to which it complies with human rights norms and standards, particularly those applicable to the right to health;
 - (b) the amendment of the legal and policy framework through measures to:
 - (i) remove barriers to access to medicines, including measures mandated by a human rights impact assessment of bilateral and multilateral trade and investment agreements;⁷⁰ and
 - (ii) integrate universal health coverage into the framework to ensure its recognition as an indispensable tool for ensuring access to health care, goods and facilities.

VI. Conclusion

41. Human rights norms and standards embody some of our most cherished values, and the international community has repeatedly confirmed their importance. As such, policy incoherence in public health, trade and intellectual property laws and human rights can and should be resolved by reference to human rights. In formulating its recommendations, we urge the Panel to endorse an interpretation of State obligations under intellectual property and trade laws which is concordant with human rights, particularly the rights to life and health, the prohibition on cruel, inhuman and degrading treatment and the right to enjoy the benefits of scientific progress and its applications. In doing so, the Panel would also

⁶⁵ ILO Medical Care Recommendation, 1944 (No. 69), para. 19.

⁶⁶ ILO Medical Care Recommendation, 1944 (No. 69), para. 20.

⁶⁷ ILO Social Protection Floors Recommendation, 2012 (No. 202), para. 4.

⁶⁸ ILO Social Protection Floors Recommendation, 2012 (No. 202), para. 5.

⁶⁹ See Technical guidance on the application of a human rights-based approach to the implementation of policies and programmes to reduce preventable maternal morbidity and mortality (A/HRC/21/22), para. 30.

⁷⁰ Report of the Special Rapporteur on the right to health (2009), A/HRC/11/12, para.16.

underscore the intrinsic and practical value of integrating a human rights-based approach into all areas of public health programming and policy with the goal of ensuring access to medicines for all.